Exhibit G

CAUSE NO. 2013-DCL-3511-D

SANDRA GARCIA, Plaintiff,	§	IN THE DISTRICT COURT
v.	§	
RODOLFO J. WALSS, M.D., RODOLFO J. WALSS, M.D., P.A., JOHNSON & JOHNSON, INC. and ETHICON, INC., Defendants.	§	103rd JUDICIAL DISTRICT
	§	CAMERON COUNTY, TEXAS

ORAL DEPOSITION OF TIMOTHY A. ULATOWSKI, M.S., a witness herein, called by the Plaintiff for examination, taken by and before Ann Medis, Registered Professional Reporter and Notary Public, at the offices of Drinker Biddle & Reath, LLP, 1500 K Street, N.W., Washington, D.C. 20005-1209, on Tuesday, June 2, 2015, commencing at 9:19 a.m.

APPEARANCES:

CLARK LOVE HUTSON, GP
BY: WILLIAM W. LUNDQUIST, ESQUIRE
440 Louisiana Street, Site 1600
Houston, Texas 77002
713.757.1400
wlundquist@triallawfirm.com
Counsel for the Plaintiff

(By phone)
SHEPHERD SCOTT CLAWATER & HOUSTON LLP
BY: CYNTHIA L. FREEMAN, ESQUIRE
2777 Allen Parkway, 7th Floor
Houston, Texas 77019
713.650.6600
cfreeman@sschlaw.com
Counsel for Defendants Rodolfo J. Walss, M.D., and Rodolfo J. Walss, M.D., P.A.

BUTLER SNOW LLP
BY: CHAD R. HUTCHINSON, ESQUIRE
Renaissance at Colony Park
1020 Highland Colony Parkway, Suite 1400
Ridgeland, Mississippi 39157
601.985.4401
chad.hutchinson@butlersnow.com

BUTLER SNOW LLP
BY: KERI I. SUTHERLAND, ESQUIRE
1200 Jefferson Avenue, Suite 205
Oxford, Mississippi 38655
662.513.8000
kari.sutherland@butlersnow.com
ROERIG OLIVEIRA & FISHER
BY: DAVID G. OLIVEIRA, ESQUIRE
10225 North 10th Street
McAllen, Texas 78504
956.393.6300
doliveira@rofllp.com
Counsel for the Defendant Ethicon, Inc.

* I N D E X *

* INDEX OF EXHIBITS *

NO. DESCRIPTION PAGE

(No Deposition Exhibits were marked.)

TIMOTHY A. ULATOWSKI, M.S.
having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MR. LUNDQUIST:

Q. Sir, can you state and spell your name for the record, please.

A. Timothy, T-I-M-O-T-H-Y, Ulatowski, U-L-A-T-O-W-S-K-I.

Q. Am I correct, sir, you're serving as a regulatory expert for defendants Ethicon and Johnson & Johnson in the Sandra Garcia case?

A. That's correct.

Q. Roughly how many times have you been deposed, sir?

A. It's getting up around a couple dozen, I think.

Q. How many depositions have you given in transvaginal mesh cases?

A. A couple, two or three.

Q. My understanding is you've never testified as an expert witness on behalf of anyone other than industry; is that true?

A. Deposition, no. I've represented plaintiffs. In court, let me think about that.

I've represented plaintiffs in court.

Q. In an expert witness capacity?

A. As an expert witness.

Q. Tell me about that.

A. Well, a couple times where actually the plaintiff was a company, so it would be a contract dispute or something of that sort, issues like that.

Q. Let me try it a little differently. That's a fair point. Have you ever served as an expert witness for an individual?

A. Yes.

Q. What individual?

A. Well, I think they settled. I don't know if I was disclosed. I think I've been disclosed in one, maybe two cases. One is a pension fund. The other one where I've been disclosed is a number of patients, and GranuFlo is the product.

Q. And you're representing an individual plaintiff in those cases? Let me restate that. That was a bad question.

You were the expert witness on behalf of the individual plaintiffs in those cases?

A. That's correct.

Q. Again, were you testifying -- when I say industry, do you know what I mean?
A. Yes.
Q. Were you testifying against industry in those cases?
A. Against the particular manufacturer, yes.
Q. What was the general basis -- what was the general crux of your opinions in those cases?
A. Regarding the conduct of the manufacturer in regard to its performance over time with respect to that GranuFlo product, what they knew and how they conducted business over the years, their reporting of complaints.
Q. Was it your opinion that they fell below -- your opinion was that the manufacturer -- tell me what your opinion was in that case.
A. My opinions typically are regulatory based. Their conduct did not meet regulatory requirements and industry standards, industry practices for the particular area of my comment.
Q. The last time you were deposed in a transvaginal mesh case, was it December of 2013, or was it more recent?
A. It's been a while. I can't tell you

exactly when.
Q. Over a year?
A. Oh, yes.
Q. What did you do to prepare for your deposition today, sir?
A. Read material, had a meeting with counsel yesterday, very, very, very brief.
Q. How long was that meeting?
A. Yesterday?
Q. Yes, sir.
A. About three, three and a half hours.
Q. What material did you review?
A. Well, we basically went over the reference material. Certain reference material was provided to me, and I reviewed that reference material.
Q. Are you talking about the reference material listed on your reliance list?
A. Correct.
Q. Specifically what do you have a recollection of going over?
A. The history of products.
Q. When you say the history of products, what do you mean?
A. The history of Prolene, of TVT devices,

of related mesh.
Q. What did you look at specifically related to TVT-Secur?
A. Yesterday or at any point?
Q. Yesterday.
A. Well, I did some refreshing of my memory myself on various documents provided to me previously. So I looked at a number of documents regarding TVT.
Q. Sure. What did you look at?
A. The labeling, the submission, certain design history file records, certain issue reports, information, that sort of information.
(There was a recess in the proceedings.)
BY MR. LUNDQUIST:
Q. We were talking about some of the things you reviewed in preparation for today's deposition specifically related to the TVT-Secur. One of them you mentioned is the labeling. I assume that's the IFU?
A. Right.
Q. What were some of the other things that you reviewed specifically related to the TVT-Secur?
A. Well, the information I personally

reviewed not with counsel, prior to the meeting with counsel was, as I said, the labeling, submission for TVT-Secur.
Q. And by that you mean?
A. Submission to FDA, risk management reports, FMEAs, other design history type documents, clinical expert reports, that sort of information. And then I reviewed a lot of the same stuff, the history, rather, yesterday with counsel.
Q. Did you look at the entire design history file of the TVT-Secur?
A. No.
Q. Have you at any point?
A. I don't believe so.
Q. What portions of the design history file -- you mentioned a few of them. What other portions of the design history file have you reviewed?
A. There were a number of documents. Like I said, there were FMEAs, risk management documents, design input documents, verification/validation tests, information about the sheep study, the cadaver studies. I have to look to see exactly.

Q. Just curious, was there a reason why you reviewed certain portions of the design history file and not the rest?
A. I reviewed what I had.
Q. You never reached out to Ethicon and asked, hey, I'd like to see the remaining portion of the design history file?
A. Yes, I have.
Q. And that's not yet been provided to you?
A. No.
Q. Have you ever given prior depositions?
A. Not for this litigation. Any prior depositions of?
Q. Of yourself.
A. Of myself, no. Now that you tweaked my memory, I did review some depositions related to this litigation.
Q. Was that in your meeting with counsel?
A. No, prior to meeting.
Q. When were you first retained by Johnson & Johnson/Ethicon in this case?
A. In this litigation? That's a good question. Probably last year sometime I would expect.
Q. Who were you retained by?

A. Butler Snow.
Q. Who particularly at Butler Snow?
A. Ms. Sutherland was my connection.
Q. What were you asked to do?
A. To evaluate records and to formulate opinions for the purpose of the statement regarding the litigation that I was provided. And fundamentally that's it.
Q. You say regarding the purpose of the statement regarding litigation you were provided. What were you provided?
A. Well, counsel provided a declaration, whatever is the term, in regard to this litigation concerning my background, basically what I would be contributing to this litigation.
Q. Are you talking about the designation of experts?
A. Yes; correct.
Q. So the designation of experts was prepared by counsel for Ethicon and given to you as an outline of what you would be expected to testify in this litigation?
A. No. It's quite the opposite. That document is created under my supervision. I elaborate to them what I think is appropriate for

them to state, and then they provided me it without typos and things like that.
Q. Maybe I misunderstood. I think you testified you were asked to evaluate records and asked to formulate opinions for purposes of the statement regarding litigation that you were provided. That indicates to me that you were actually provided with an outline of what you were expected to testify.
A. That's incorrect.
Q. Tell me what it is -- maybe I'm confused here. What did you do?
A. Well, with every litigation I enter the litigation with a blank check -- with a blank mind on my opinions and beliefs regarding that litigation. I receive documents concerning that litigation. I evaluate those documents. And then at a point in time, when I've looked at those documents, then a statement is constructed under my supervision.
Q. Are you saying you prepared the statement set forth in the defendant's expert designation?
A. I provided the construction of and elements of that document. The background

information, all that is cut and pasted from my CV, for the most part.
Q. The sum total of your substantive opinions are about a paragraph?
A. Right.
Q. Now, obviously you incorporate some of the testimony that we're not really going to talk about hopefully today from your previous cases. I assume today's testimony would be in line with that?
A. Yes.
Q. How much time have you spent working on this case?
A. I really haven't added up my hours. I'd be speculating.
Q. You have no idea? More than five hours?
A. Oh, certainly.
Q. More than ten?
A. Well, I'd hazard -- I know it's not appropriate to guess in all cases, but I'd hazard a guess between 30 and 50 hours, maybe more.
Q. Have you submitted any bills for that time?
A. Yes.
Q. Did you help any of Ethicon's attorneys

Page 14

secure any other experts in this litigation?
A. I don't believe so.
Q. Have you ever spoken with any Ethicon employees?
A. I don't believe so.
Q. I want to clarify this. To the extent that you know that you've been designated as an expert by Ethicon, how many other current cases or past have you acted as an expert witness on behalf of the defendants in this case?
A. Well, there's various litigations over the four plus years that I left FDA. Individual litigations, I'd say between five and ten on TVT or gynecological mesh in general.
Q. What about taking transvaginal mesh out, how many other times have you acted as an expert?
A. I think the sum and substance has been regarding OB-GYN devices, TVTs, pelvic meshes. And in addition, hernia mesh has been another area. There's been a few litigations there.
Q. If you're talking five to ten on gynecological mesh, how many are we talking hernia mesh, any other type of testimony you want to talk about, sir?
A. Well, some of them were nonstarters

Page 15

because they settled. So I'd say actually went to a report, three to five maybe.
Q. I'm not so concerned if a lot of cases settled. I'm just asking if you know you've been designated as an expert on any other cases outside of these five or ten gynecological mesh cases we're talking about regardless of whether they settled.
A. Well, I'm not a lawyer, but if it never got to a report submission and it settled, I guess I was never designated at a point in time. I just don't know. All I can say is I've submitted reports three to five times.
Q. Outside of these five or ten we're talking about on TVT-related mesh?
A. Right.
Q. How much have you been paid as an expert by Ethicon, best guesstimation?
A. I couldn't hazard a guess.
Q. Over a hundred thousand?
A. I would say so.
Q. Have you talked to any of Ethicon's other experts in this litigation?
A. No.
Q. How were the documents that are listed in your reliance list selected, do you have any

Page 16

idea?
A. Some were provided by counsel at the outset. Some I request over time based upon what I've been evaluating. So it's a mix.
Q. What are the types of documents you request over time?
A. Documents that may be in plaintiff's experts' reports, documents I come across that are referenced in other documents, deposition exhibits that I may not have that I need, things like that.
Q. So you looked at -- let's take Dr. Parisian, for example. You looked at her transcript in the case?
A. Yes, I did.
Q. You looked at the whole deposition?
A. Yes.
Q. Were there any documents that she discussed or were exhibits to her deposition that you said, hey, I'd like to see what she's talking about?
A. I don't recall. I've seen, you know -- I've had prior litigation. So I'm not sure there's anything new in her deposition.
Q. So the issue she was talking about specific to TVT-S, you didn't think there was

Page 17

anything new that you hadn't heard of before?
A. I've been provided a great deal of TVT-S data. I've seen prior depositions. I don't think there's anything particularly, in addition, that I saw being discussed in her deposition I hadn't already seen in some way, shape or form already.
Q. Nothing that concerned you about what she was testifying related to the documents that she was talking about?
A. Not that I can recall. I may be in error, but not that I can recall.
Q. And I appreciate you can't recall. You understand that one of the purposes for today's deposition is understanding everything you know before trial. You didn't prepare an expert report in this case. This is really my only opportunity to talk to you. You understand that?
A. I understand that.
Q. And certainly you understood in meeting with counsel yesterday that part of what you would be expected to talk about today is the basis for your opinions?
A. Yes.
Q. I'm not going to expect that you have a perfect memory about every document you reviewed,

Page 18

sir, but to the extent -- I am expecting you today to the extent that you do have any basis, we talk about your specific opinions and the basis for those opinions, that you are going to be in a position to articulate those.

Do you feel comfortable that you're going to be in that position today?

A. I probably need the support of certain documents to refresh my memory, because, of course, I haven't produced a list of opinions that I can relate to you specifically, and make sure that they are all the types of opinions I would express.

Q. Do you intend to offer any opinions on any of the plaintiff experts' reports or testimony?

A. Could you repeat that?

Q. That was not a great question. Do you have any opinions that come to mind about Dr. Parisian's transcript, her designation or the transcript?

A. Well, it's quite a lengthy transcript. I think I have to have that transcript in front of me to page through it to identify the areas where I may have some impressions, comments.

Page 19

Q. I'm still going to ask you every opinion that you have today related to Dr. Parisian's testimony. So tell me what those are.

A. I think to be fair to myself, I would need to have that transcript in front of me and go through it because I have no notes here.

Q. So what you're telling me sitting here today, you have no ability to tell me any opinions you have one way or the other about Dr. Parisian's transcript?

MR. HUTCHINSON: Object to form.

A. Not with great clarity because, again, I haven't produced an opinions list. I haven't referenced her transcript. I know that she covers ground that plaintiff's experts cover in regard to labeling, in regard to submission, in regard to reports to FDA.

BY MR. LUNDQUIST:

Q. You mentioned two or three of those. Tell me, do you agree or disagree with any of her opinions on the labeling front?

A. Well, I think in addition to Dr. Parisian, I think plaintiff's experts -- I have a very narrow view of the relevance of labeling to what a physician knows regarding a

Page 20

product.

Q. What other depositions did you review besides Dr. Parisian and Dr. Walss and Ms. Garcia?

A. Those are the depositions that refer to this litigation.

Q. Sure. What are you talking about?

A. I'm talking about other plaintiff's experts. They're very similar to Dr. Parisian when they're plaintiff's experts on TVT cases.

Q. Are you talking about Dr. Klosterhalfen?

A. No.

Q. Who are you talking about?

A. I think Dr. Pence has probably opined about the same sorts of issues that Dr. Parisian has opined about.

Q. Dr. Pence wasn't retained by Ms. Garcia in this case. Dr. Parisian is. I understand you read her expert report, presumably not in connection with this litigation, but I'm just trying to understand any and all thoughts you have on Dr. Parisian's opinions, whether or not you agree with them, you disagree with all of them, any and everything.

A. Well, I think you have to hear the preface to my comment where I said that

Page 21

Dr. Parisian has comments similar to others. So let me talk about Dr. Parisian, at least to the extent I can, but knowing full well that these may not be the extent of my opinions because I don't have the transcript in front of me. But let me talk about labeling just for a moment. Labeling serves a purpose.

Q. Doctor, I'm asking you concerns with Dr. Parisian's transcript. We're going to talk about your opinions in a moment. I just want to see if you have any agreements or disagreements with Dr. Parisian, generally speaking. I'm not telling you to list a hundred disagreements you've got. I want to understand conceptually what your agreements or disagreements are. Fair?

A. That's exactly what I was doing.

Q. I'm sorry to interrupt you. Please continue.

A. Dr. Parisian makes several comments about labeling. Labeling is an instrument that is required by FDA regulations. It has ingredients that are required by regulation. The labeling that Ethicon has for TVT-Secur meets those regulations.

Labeling alone -- labeling is not the only

Page 22

source of information to a physician, which I think is downplayed by Dr. Parisian. In fact, Dr. Walss testified to this, that labeling is one source of information for a doctor.

Training, experience, the literature, other sources of information are in many ways just as valuable as labeling. In fact, Dr. Walss testified that he read the literature. He learned a lot from the literature, kept up to date on the literature on what were the current clinical experience, risks and benefits of TVT-S. I think that was an important point.

So is labeling the sum and substance of information for a doctor on the risks and benefits of a product? Then the answer is no.

Q. So you disagree with Dr. Parisian's opinion that the labeling was inadequate?

A. No, I do not. I'm not a doctor, so I cannot put my views in terms of how a physician may view the labeling. But, for example, experience plays a large part in what a doctor understands about risks and benefits.

TVT devices generally, like TVT-Secur, its risks are not unlike other procedures, non-TVT procedures. The only difference is mainly things

Page 23

like erosion. So he certainly was experienced in Burch and other procedures where they have the very same types of risks.

Speaking of erosion, he certainly wasn't taught by Ethicon on how to deal with erosion, as he testified. Pain, I'm not a physician, but to understand that all surgery incurs some degree of pain, post-surgical pain, in fact, the good doctor prescribed analgesics for pain. So if he didn't believe there was post-surgical pain, why were those prescribed.

I mean, there's lots of things a doctor understands in my experience in working with doctors over 40 years on many products, what a doctor understands, where a doctor gets his or her knowledge about a product. So to think that labeling has to be a medical textbook on its face is absurd. But to be inclusive of every bit of information is not realistic. A lot of information -- actually the literature is more up to date than IFUs in many, many cases.

So the issue reports and MDRs, I looked at issue reports submitted on TVT-Secur. I looked at the MDR submitted for TVT-Secur. It was evident to me that Ethicon was being very responsive to

Page 24

their obligations to receive and analyze complaints, to track complaints, to submit MDRs as required, and there were numerous MDRs that Ethicon submitted for TVT-Secur and for other TVT devices.

Q. Doctor, with all due respect, I'm going to object. It's not responsive after "No, I do not."

I wanted -- one thing your previous testimony makes clear. I noticed you weren't provided with any medical records in this case, true?

A. I don't believe so.

Q. And presumably because you're not a medical doctor; right?

A. I did have some medical records, operative reports, I believe.

Q. I'll represent to you that they're not listed in your reliance list, but that aside --

A. I may be in error, but I think I did have an operative report.

Q. But you're not a medical doctor; right?

A. That's right.

Q. You have no medical training, true?

A. I do have a master's in physiology from Georgetown Medical School. So it's a

Page 25

medically-oriented course and an engineering-oriented course as well.

Q. Sir, you previously testified you can't render any opinions as to whether or not Ethicon acted reasonably in what they did or did not disclose in their IFUs, patient brochures or marketing materials because that would necessarily require medical opinions; is that true?

MR. HUTCHINSON: Object to form.

A. I think in regard to how a doctor interprets that label, that's certainly the case.

BY MR. LUNDQUIST:

Q. You're standing by previous testimony, true?

MR. HUTCHINSON: Object to form.

A. Yes. I'm not a doctor, so I can't get into a doctor's head on how they interpret certain terms.

BY MR. LUNDQUIST:

Q. And you don't intend to offer any clinical or medical causation opinions in this case, true?

A. True.

Q. So where your designation says you're going to talk about medical device labeling,

Page 26

regulations and industry standards related to TVT-Secur, I'm guessing that one of your opinions is that the TVT-Secur IFUs or instructions for use inform, met the FDA's regulatory requirements for prescription labeling; is that true?
A. That's correct.
Q. And that's similar to opinions you've given in the past on other Ethicon IFUs?
A. Yes.
Q. Again, based on your previous testimony, you don't have an opinion in this case on the accuracy or completeness of, let's say, the adverse reaction section of the TVT-Secur IFU because that would necessarily require a medical opinion, true?
MR. HUTCHINSON: Objection.
A. I think you just heard what I think about labeling and how in my experience doctors are advised about information. I certainly had that role and function and expertise in my 40 years so far dealing with medical devices and labeling issues over those years. So I'm not interpreting the labeling as a doctor would.
I'm just indicating to you the context of labeling within the totality of information that a

Page 27

doctor is provided on a product.
BY MR. LUNDQUIST:
Q. With respect, Doctor, I'll object. Mr. Ulatowski, I'll object as nonresponsive.
I just want you to agree with me that you don't have an opinion on the accuracy or completeness of the adverse reaction section of the TVT-Secur IFU.
MR. HUTCHINSON: Object to form.
A. To the extent it meets regulatory requirements, I certainly do. But as far as specifics and how a doctor would interpret the terms, no, I don't interpret the labeling in terms of a doctor.
BY MR. LUNDQUIST:
Q. That would require a medical opinion as you previously testified, true?
A. I think it would to fully elaborate on the labeling. I think I would add that more specifically, I think an OB-GYN, gastroenterologist -- OB-GYN, rather, would be best oriented to comment on that particular --
Q. Further, based on your previous testimony, you don't have an opinion or the expertise frankly to opine as to whether the

Page 28

TVT-Secur IFU adequately disclosed the risks that were known to medical affairs, true?
MR. HUTCHINSON: Object to form.
A. To the extent it met regulatory requirements and FDA cleared the product including the labeling and the submission, I think on that basis certainly met FDA's expectations regarding adequate prescription labeling.
BY MR. LUNDQUIST:
Q. Again with respect, sir, nonresponsive.
I understand what your opinions are on hey, it met the regulatory requirements, it checked the box. I agree it passes muster on the regulatory requirements.
I want to make clear you don't have the expertise to opine as to whether the TVT-Secur instructions for use adequately disclosed the risks that were known to medical affairs. Is that a true statement?
MR. HUTCHINSON: Object to form.
A. Well, let me play off your comment of checking the box. FDA's review is more than checking a box. Let me explain to you what I did virtually every day for 25 years in device evaluation, in evaluating devices.

Page 29

You look at the labeling. You evaluate the labeling. You look at the indications, the precautions, the warnings. You get clinical input from your co-reviewers on the labeling. There's an evaluation label. It's trivializing FDA review to say check the box. It met regulatory requirements, and it met it because it had an adverse reaction section that met FDA's expectations.
MR. HUTCHINSON: Objection. Nonresponsive.
Can you please read back my question.
(The record was read back.)
MR. HUTCHINSON: Object to the extent it's been asked and answered.
BY MR. LUNDQUIST:
Q. You can answer.
A. I think I made it clear as to --
Q. I assure you you did not. You previously testified. You just answered "Yes." I'm just trying to understand if your opinion on the TVT-Secur IFUs can be different than on the TVT IFU. I assume it's not. That's all I'm getting at.
MR. HUTCHINSON: That's a different

Page 30

question, with all due respect.
MR. LUNDQUIST: Read him the question back, please.
(The record was read back.)
MR. HUTCHINSON: Same objection. It's been asked and answered.
A. I already explained that I'm not a doctor and I would not view the labeling with the orientation of a physician, particularly an OB-GYN.
What I was additionally commenting on, that based on my experience on how this labeling gets reviewed, that it would have been evaluated clinically and to the satisfaction of FDA. So that clinical evaluation would have occurred, not by me but through the process.
BY MR. LUNDQUIST:
Q. You talked about your review of the FMEA that was part of the design history file part of the TVT-Secur. And you previously testified concerning other medical devices including the 510(k) process. Do you have an opinion -- strike that.
You have no opinion sitting here today, sir, whether Ethicon's internal DDSA or FMEA process is

Page 31

evaluating each of the medical risks associated with the TVT-Secur device, true?
A. Not being a doctor, I think typically FMEAs, DDSAs, whatever term you might use, and there's various types of FMEAs, require a team effort to identify hazards. So inasmuch as my expertise takes me, I could evaluate what was submitted in those FMEAs in terms of thoroughness, in terms of structure, in terms of how they analyze the hazard.
But to say what a doctor brought to the table of additional hazards, I'm not a doctor, so I can't say. I know that Ethicon in these FMEAs and risk documents are not static. They get reevaluated from time to time, as Ethicon did which I saw in the clinical expert report.
Q. Maybe we're having trouble communicating, sir. I'm going to talk to you about the basis for your opinions and your opinions in a little bit. I'm trying to get a general framework here.
You previously testified you would have to do a medical assessment necessarily to evaluate the DDSA and the FMEA processes. I want to make sure your testimony is consistent with previous

Page 32

testimony, sir. So I'm going to ask the question again. I'm not interested in what Ethicon did. I'm not interested in the regulatory process right now. I'm interested in whether or not you agree with me on an issue that you previously testified on another device.
And that is: You do not have an opinion whether Ethicon's DDSA or FMEA processes evaluated each of the medical risks associated with the TVT-Secur device. Is that a true statement or not?
MR. HUTCHINSON: Object to form.
A. I think you asked that question, and I believe I answered it to the best of my ability in saying -- prefacing, again, that I think there's a -- it's a team effort where there is a medical input. I'm not a physician. So to analyze the entirety of the FMEA from a clinical perspective, I don't think I could do that in total. So that's consistent with my prior testimony.
BY MR. LUNDQUIST:
Q. I agree. I think what you're saying -- correct me if I'm wrong -- you're saying that Ethicon was compliant in these procedures that were supposed to be in place, like the DDSA and

Page 33

the FMEA, but you're not offering opinions with regard to the actual application or conclusions drawn through those processes, true?
A. It's more of a process, regulatory process, standards process, industry practice process. Creating the FMEA, identifying all the hazards, mitigating those hazards, reviewing those hazards from time to time, that's the process, and that's a process Ethicon did.
Q. Again, sir, I agree. You're talking about the process, the procedures. My question is far more specific. I'm going to try it one more time. I've tried a few times here.
You're saying Ethicon was compliant with these procedures. I'll give you that. That's consistent with your previous testimony. I want to make clear in this case that you're not offering any opinions with regard to the actual application or conclusions that were drawn through those processes. Is that a true statement?
MR. HUTCHINSON: Object to form.
A. I think in regard to the specific FMEA, specific hazards, not having expertise in all the areas of FMEA, that would be true. On the other hand, as a basis of the purpose of the FMEA and

Page 34

how it's utilized in the process of bringing a product to market, it certainly was complied with by Ethicon.

MR. LUNDQUIST: I'll object as nonresponsive after "that would be true."

BY MR. LUNDQUIST:

Q. Doctor, I gave you purpose and procedure and all that. I'm trying to move through this deposition as quickly as I can.

You're saying they were compliant. What were they compliant with?

A. Well, everyone pretty much in the industry follows the risk management standard and the tools outlined in that standard in regard to evaluating hazards and mitigating hazards, and the standard is not prescriptive. The standard doesn't say you have to have the following hazards. You have to have all this thorough and complete, because it's an iterative process.

The standard lays it out there generally, and the companies as an industry practice take up that standard and apply it in their case. So I don't think there's any FMEA that I've ever viewed, just as a general rule in my experience, that ever had all the hazards ultimately encountered with a

Page 35

device in all the initial FMEAs because it's an reiterative process.

You come back to the FMEA. You consider hazards. You add hazards. So it's a process issue. So inasmuch as it touches on your point, so be it, but again, it's a process issue.

MR. LUNDQUIST: Objection. Nonresponsive.

BY MR. LUNDQUIST:

Q. My understanding, sir, is that as the former head of the Office of Compliance at the FDA, you relied on others at the Center for Devices and Radiological Health that had training to look at corporate documents like the FMEA, true?

A. It's always a team effort, yes, at FDA.

Q. The answer to my question is "Yes"?

A. Yes, but not always.

Q. Did you ever personally look at corporate documents to determine compliance with FDA's regulations?

A. Of course.

Q. Tell me any instance you can recall where you personally, sir, looked at corporate documents to determine compliance with

Page 36

regulations.

A. Well, just a point. Director of Compliance is the final authorizing person on any enforcement action by FDA for medical devices. I saw every enforcement action related to every medical device company. I had to review the entire file. I had to review all the procedures and policies. I had to confirm that any observations identified, any charges levied were appropriate. I was the final signatory.

Q. Right. But you acted as the officer of compliance based on the recommendations of others within the FDA?

A. Of course, there were recommendations, but they didn't hire me as a history major. I was a biomedical engineer and a microbiologist trained in the quality system process. So I was fully capable and authorized and responsible for evaluating those same documents. I trained people on the quality system, on procedures and policies, on FMEAs, on risk management documents. For FDA I've trained them.

MR. LUNDQUIST: Nonresponsive after "recommendations."

Page 37

BY MR. LUNDQUIST:

Q. I want to go back to your point, your testimony -- you appreciate you're under oath today just as if you were sitting in front of a jury today?

A. Sure.

Q. You're saying that you personally looked at corporate documents to determine whether or not there was compliance with FDA regulations.

A. I did that all the time. I still do as a consultant.

Q. Give me an example of what you did when you were at the FDA when you actually looked the corporate documents themselves.

A. Well, when evidence is provided to attempt to support an advisory action which are called warning letters or title letters, or when an enforcement action is coming down the pike, enforcement action, seizure, injunction, civil money penalty, those documents are indeed evaluated by lower level staff because, of course, how can one person evaluate all those various documents that come into FDA.

But during the course of those evaluations and at the end of that chain was me to accept or

reject any recommendations, any evidence, any charges before letters would issue, or whether the case would proceed to the Department of Justice. So I necessarily had to have expertise. I did, and I applied it.

Q. I'm still looking for an example, sir. Any time you can recall specifically looking at the corporate documents themselves in your role?

MR. HUTCHINSON: Excuse me. Can we go off the record for just a second.

(There was a discussion off the record.)

BY MR. LUNDQUIST:

Q. Mr. Ulatowski, I'm still looking for just an example. I appreciate you may have some confidentiality issues, but I'm just trying to understand a little bit more in depth what it is you did while you were -- in your role as the --

A. Director of the Office of Compliance.

Q. And when you individually would have actually looked at corporate documents.

A. Again, for every warning letter that issued under my signature, for every enforcement action that issued under my signature, before it advanced to general counsel and to Department of Justice, those would have been under my direct

evaluation of corporate documents.

Procedures, policies, evidence, samples, affidavits, every piece of evidence according to the particular case I would have to evaluate and sign off on before I allowed that document to proceed to final, my final signature in many cases, or to proceed onward for further litigation.

Q. Your testimony, as I understand it, you had to sign off on that to move forward. I get all that. Your testimony is you physically looked at these internal corporate documents to determine whether or not there had been compliance with FDA regulations?

A. Absolutely.

Q. Did you ever find any that had not complied?

A. I guess I don't understand your question.

Q. Upon your review of these corporate documents, when you were determining whether or not whatever company had complied with FDA's regulations, did you ever reach the decision that, in fact, they had not -- any company had not complied with FDA's regulations?

A. I was the director of compliance. What was coming to my desk always were companies that were out of compliance in one way, shape or form. So I may have rejected a charge based upon my review of the evidence. I may have added a charge, and I did, based upon my review of the evidence. So that's typically what happened.

Q. I forgot to mention earlier, sir -- we were talking about some of the documents you looked at. I noticed you reviewed some Ethicon employee testimony as well.

A. Along the way, yes.

Q. Any in preparing for this deposition?

A. I didn't go back to refresh my memory about it, but, yes, I've certainly seen a whole lot of depositions of Ethicon employees.

Q. Did you rely on any of these Ethicon corporate witness depositions to support any of your opinions in this case?

A. Well, it's hard to segregate one's views and position when you have the totality of information you've looked at for the same types of devices in your brain.

Q. Give me any testimony you relied on in forming the basis of your opinions in this case,

sir.

A. I think what's very important is the testimony of the medical directors when they evaluated labeling, when they constructed labeling, what their views were. I'm not a doctor. Interesting to see how they viewed the labeling and what they believed to be the case with labeling through their eyes.

Q. So you're talking about Charlotte Owens, David Robinson and Peter Newell?

A. I think Weisberg is in there.

Q. Marty Weisberg?

A. Yeah.

Q. That testimony stood out as important to you because what they had to say with regard the TVT-Secur was important to you?

A. In regard to TVT-Secur in general and the labeling because the labeling for the TVT devices in many respects -- of course, there are differences, but in some respects they're very similar. But understanding their opinions on the labeling and construction of labeling is very important. That's one segment.

Of course, the other segment are the quality people, the manufacturing people. It depends on

Page 42

what the opinion was that I was -- or the regulatory people. It depends what my opinion was related to.

Q. You keep going back to the TVT devices, and really my question -- I know you've been questioned thoroughly about your opinions on the TVT-O, TVT, all the predecessor devices. We'll talk about those briefly in a moment.

But is it a true statement when I asked you their testimony, again, Owens, Robinson, Newell, Weisberg, their testimony stood out as important to you on the TVT-Secur labeling?

A. Yes, in general, and specifically Weisberg did the initial CER. Robinson did some CERs later on TVT-Secur. And Newell did a CER on Secur. They had deposition testimony all along the line of production of TVTs from even before '98 when the TVT classic came out. So their perspective I think is important, their views.

Q. What was your takeaway on their perspective on the TVT-Secur?

A. I think that the risks were adequately identified in the labeling, that they were consistent in their belief regarding -- as I spoke to earlier, that labeling is but one element of

Page 43

the knowledge base of doctors and how they interpret certain terms in labeling. So that's consistent with TVT-Secur and their deposition testimony, as I recall.

Q. So your recollection is that they believe the risks were adequately identified on the labeling in the TVT-Secur?

A. I believe so, yes.

Q. Any other testimony that you would have relied on in forming your opinions in this case?

A. Well, as I said, there's other groups of people that are of interest to me as I evaluate documents, the regulatory people, the quality staff that are engaged in the history files.

Q. What did they say that was important to you?

A. The regulatory people are concerned with the submission process, what needs to be in the submission, what's taken from the history file and other records to form the submission that's provided to FDA, what's the strategy for providing -- I'm not finished -- what's the strategy for bringing this product to the marketplace, is that consistent with regulations and practices in the industry.

Page 44

Q. Do you have an understanding of what their strategy was in bringing the TVT-Secur to the market?

A. Well, fundamentally it's here we have a modification of existing TVT devices. This particular device has particularly unique benefits in their mind regarding -- compared to the other devices, and that formed the basis of proceeding with the particular product.

Q. Did it have unique risks as well in their mind based on your review of the testimony?

A. I think the risks, as I recall testimony, of TVT devices in general are very, very similar.

Q. Not my question, doctor. Did the TVT-Secur have unique risks based on your review of their testimony?

A. I don't believe so.

Q. Which regulatory employees stood out most to you?

A. Well, I was interested in Hojnoski, of course, because she was connected to this. But along the chain, there were other people that came in and out in the deposition testimony on TVT devices. She kind of stands out in my brain for

Page 45

the moment, emails or whatever was associated with it.

Q. You're not going to be offering opinions on any medical malpractice issues in this case, true?

A. True.

Q. Not an expert on polypropylene?

A. No. I'm not a materials engineer.

Q. Not going to be talking about pathology issues?

A. Not a pathologist.

Q. If something is not on your reliance list, can I assume that you did not rely on it in forming your opinions?

A. That would be a fair statement.

Q. You do consider yourself an expert in the 510(k) clearance process?

MR. HUTCHINSON: I'm going to object. I don't know exactly what reliance list you're reviewing. So I just want to object.

MR. LUNDQUIST: This is what was produced.

A. Yes.

BY MR. LUNDQUIST:

Q. Tell me what your opinions are in this

Page 46

case, Doctor.
A. Well, again, it would be difficult for me to enumerate all of them, maybe even most of them because I don't have particular notes. I certainly opined in previous reports on TVT devices, but, of course, this is TVT-Secur. It's a different device.
This device was brought to the marketplace through a 510(k). 510(k) itself, traditional 510(k), so-called traditional 510(k), this traditional 510(k) was complete. It was thorough, met all FDA expectations, regulatory requirements for a 510(k). It included the type of comparison information, the predicate information, the sort of test data that FDA expected in a 510(k) of this type, descriptive information as I said, the labeling. The surgical technique certainly was appropriate, and FDA cleared it, I think, appropriately based upon that information in my experience.
Related to that, I was interested to see that FDA did a thorough review of the 510(k) as evidenced by the interaction of the evaluators of the company, Dr. Herrera, Dr. Lerner, in evaluating the technique, the information that was

Page 47

submitted. FDA sent an additional information letter to Ethicon asking for more detail, clinical, engineering data, additional engineering data. Certainly not a rubber stamp, this is a highly technical clinical review process.
Ethicon submitted that information at a meeting with Ethicon in between. FDA evaluated that information and cleared the device. At all points in time during the 510(k) review process, FDA is in charge. FDA is the gatekeeper on the submission. What information it needs it will get. In fact, it asked for information. It received information.
FDA is the final arbiter. It made the decision to clear and make the product legally available to be marketed at the end of '05.
Q. No. 2?
A. And that's premarket. And that information included, for example -- and all this is kind of related. Sometimes I break these into separate opinions.
Q. You can keep talking, sir, but I understand. You've talked a lot about the 510(k) process and what has been submitted. So I appreciate your opinion is they met, that the --

Page 48

help me I understand if I'm stating your opinion correctly, that Ethicon's 510(k) submission on the TVT-Secur was properly cleared by the FDA.
A. There was an appropriate and thorough submission. It was thoroughly reviewed by FDA on a technical and clinical basis and they cleared it.
Q. Okay.
A. In addition, related to that, the type of verification/validation data submitted in that 510(k) is consistent with industry practices for not just these types of devices, but medical devices in general, for example, preclinical animal studies called the sheep studies to evaluate insertion, retention, strength, for example, the cadaver studies. These are industry standard practices. There's nothing extraordinary here.
In fact, it's commonplace and FDA recognizes that, and it's consistent with the quality system regulation.
Q. What's the basis of that opinion, sir, when your testimony -- I believe your opinion is that the validation and verification data that was submitted to the FDA is consistent with industry

Page 49

practices for these types of devices?
A. Well, after 40 years of evaluating submissions, evaluating verification and validation data, I can tell you with great assurance that this is the sort of common approach to evaluating devices, engineering data, evaluating the material properties of the product, the biocompatibility of the product based upon its longstanding performance, the animal data, evaluating the specific aspects of TVT-S which had a different manner of surgical approach.
I'm not a doctor, but certainly the inserters and the attachment was different as Dr. Herrera pointed out. Validation under the quality system regulation, all the information submitted in the 510(k) actually is derived from, for the most part, from the design history file.
The design history file is a quality system requirement, and the design history file requirements are enumerated in the quality system regulation. So if I change hats a little bit between premarket and quality systems compliance, it's because the quality system regulation really drives all the data that's developed and submitted in the 510(k). So getting back, validation,

Page 50

what's the requirement for validation?
Q. That's what I'm looking for, is the basis of your opinion.
A. The requirement is a simulated or actual use condition test. Are cadaver tests simulated tests? Of course, they are.
Q. What are you relying on for that, sir? You just told me your 40 years of experience, this is the type of thing that you would expect. I'm just trying to understand is there a statute that I could look to that says, yeah, hey, this verification, these validation testing meets muster?
What would you look to if you were someone like myself that had no experience at the FDA?
MR. HUTCHINSON: Object to form.
A. First of all, you'd have to look at the regulation itself, what does the regulation call for.
BY MR. LUNDQUIST:
Q. What regulation is that?
A. Quality system regulation that I've been talking about. Quality system regulation speaks to verification tests, speaks to validation tests. What is an appropriate validation test? It

Page 51

defines what it is. What are verification tests? Verification tests evaluate whether the product meets particular design input requirements. What are design input requirements, what are design outputs, those are all identified in the quality system regulation.
Those aspects are further defined in industry practices for a type of product, in this case for meshes, for OB-GYN meshes, tapes. As I viewed submissions and documents over the years, these are the sorts of tests that are conducted. The same sort of tests are conducted on other types of devices, very similar tests.
MR. HUTCHINSON: Objection, nonresponsive.
BY MR. LUNDQUIST:
Q. I'm trying to be a little bit more specific. You talked about the quality system regulation. Is there a specific statute? Is this CFR? Is this a subset of the FDA guidelines? What are you talking about?
A. Quality system regulations in 21 Code of Federal Regulations, Part 820.
Q. 21 CFR 820?
A. Yeah. Therein you'll find the

Page 52

requirements for design history files. Therein you'll find the requirements for verification and validation tests. Those requirements are further elaborated -- may be further elaborated in guidance documents FDA produces.
For example, there's a guidance document for surgical sutures, polypropylene sutures that further defines the sort of engineering tests and other data that needs to be submitted in a 510(k).
There's not a similar document for TVT devices, but, again, falling back on industry practices, over the years the particular industry comes to know the types of engineering tests, preclinical tests and clinical type data that FDA wants to see in a 510(k).
Q. I understand 21 CFR A20. I think I understand the guidance documents you've been referencing that may provide some understanding. If I was to look at one of these guidance documents, you're telling me it would support your position that the validation and verification data was sufficient; right?
A. Yes.
Q. You mentioned industry practices. What are you talking about there?

Page 53

A. Well, the regulation goes so far. How do you understand what verification test to do, what validation test to do. Then you rely upon what's been the norm in that particular industry to provide that evidence.
Now, there's further standards, international standards that support particular types of testing that are submitted, ISO 10993 for biocompatibility, various ASTM tests for tensile strength, material strength tests. These are commonly applied standards for medical devices in general.
Q. Again, industry practices, like you did with the CFR, I'm just trying to understand if I was to talk to the Google gods and ask them what industry practices do I need to be made aware of so I can look at what Mr. Ulatowski is talking about when he says Ethicon's verification/ validation data met muster or was sufficient in this case, I should say, what would you direct me to?
MR. HUTCHINSON: Object to form.
A. I think I mentioned standards. I mentioned regulations. I mentioned guidance. I mentioned what FDA has generally requested and

Page 54

accepted in the past. TVT-S is not the first TVT device on the market. There's a long history here of back and forth between Ethicon and FDA on the sort of information FDA expects to see in submissions for TVT devices, for mesh devices.
Q. So these industry standards are these regulations that you've been talking about?
A. Right. And FDA applies those uniformly and fairly across the particular industry. Take cadaver studies, for example, these are sorts of studies that early on in the development process are identified by the manufacturer as the sorts of validation that may be appropriate for a device.
These tests are vetted with FDA over time. FDA has seen cadaver tests before for TVT devices. You get into a rhythm with FDA on the certain types of data that FDA typically likes to see.
Q. Then the ISO 10993 I have written down. What is that?
A. That's a biocompatibility study.
Q. What requirement does Ethicon have to comply with ISO 10993?
A. There's various tests that are expected under 10993 depending on the contact conditions of the material.

Page 55

Q. I don't want to talk about the type of testing. I know about the touching the rabbits on the ears and all that stuff, and that's way off. Strike that.
My question focuses on what requires Ethicon to comply with ISO 10993.
MR. HUTCHINSON: Object to form.
A. The fundamental aspect is safety. Is this device safe? What are the risks that may occur with the device? How do you evaluate those risks? Biocompatibility testing is evaluating certain aspects of risk of the material of a product and of actually pieces of the final product in implantation tests and other tests.
BY MR. LUNDQUIST:
Q. You're telling me they're not required to do it; they just do it just because?
A. They do it because it's an industry norm to do it, industry practice. Over time FDA has found that to be a basis for meeting certain expectations on establishing safety of the particular product.
Q. I see. ISO is a -- what would you call it -- a regulation? Guidance document?
A. It's a standard, international standard.

Page 56

Q. So it would be a standard set forth by FDA for a manufacturer to show safety?
A. Yes. It's a safety evaluation series of tests. FDA has recognized the standard, and FDA has a process of recognizing standards that are -- and FDA identifies on their standards recognition website what sorts of requirements or recommendation may be met by that standard. So that's another source of information on particular standards.
Q. Does the fact that TVT-Secur was cleared signify to you, sir, that it is safe and effective for permanent implantation?
A. Yes.
Q. Part of what Ethicon has to do in the 510(k) process is demonstrate a substantial equivalent to predecessor devices, true?
A. Yes, it's as safe and effective as a predicate device. And if it is, then it's meeting the standard of reasonable assurance of safety and effectiveness.
Q. Let me make sure I understand. They have to show substantial equivalence to a predicate device, and separately they have to show it is at least as safe or effective as one of

Page 57

these cleared devices, true?
A. Yes. There has to be a predicate or predicates identified and comparisons made to that predicate or predicates. In doing so, once your 510(k) is cleared, then you've met one of the statutory requirements on determining reasonable assurance of safety and effectiveness.
Q. So your understanding is that once it's cleared by the FDA, that means that it's safe and effective. But Ethicon does not have to show that it is as safe or as effective as a cleared device?
MR. HUTCHINSON: Object to form.
A. That's the regulatory standard, as safe and effective as.
BY MR. LUNDQUIST:
Q. So that's something that you believe Ethicon also has to demonstrate with respect to the TVT-Secur?
A. Yes.
Q. What were the predicate devices that were used by Ethicon in this 510(k) submission on the TVT-Secur?
A. It was the prior Ethicon TVT devices.
Q. Which ones?
A. TVT classic and O.

Page 58

Q. Is it your opinion that the TVT-Secur was substantially equivalent to the TVT and the TVT-O?
A. Yes. Ethicon also provided information on another predicate in a response back to FDA. So there actually was I would call it three predicates at the end of the evaluation process.
Q. You're talking about when they had that interchange with Dr. Herrera and they found something from 20 years ago and said it was substantially equivalent?
MR. HUTCHINSON: Object to form.
A. They identified another predicate.
BY MR. LUNDQUIST:
Q. Do you remember when that device had been cleared? I shouldn't even call it a device. Do you remember when that product had been cleared?
MR. HUTCHINSON: Same objection.
A. It was around TVT-O time, I think back then.
BY MR. LUNDQUIST:
Q. So within the last 15 years do you think?
A. Oh, yeah.

Page 59

Q. What's the basis for your opinion the TVT and TVT-O were substantially equivalent to the TVT-Secur?
A. Well, when one evaluates the 510(k), you evaluate, first of all, the intended use of the products. Does this device, this new device have the same intended use as the other devices, the predicates? The answer to that is yes. It's for the same clinical purpose.
Q. Is it your opinion that the TVT-Secur was as safe and effective as the TVT and the TVT-O?
A. It's my opinion based upon the submission that I would have signed off on that product as cleared. And, of course, FDA did. So the answer is yes. It was as safe and effective as TVT and TVT-O.
Q. And the basis for that opinion is the clearance itself?
A. No. I never take clearance letters on their face as the basis. I always look at the submission.
Q. What's the basis for that opinion then?
A. The information provided, the engineering, the preclinical, the cadaver studies

Page 60

submitted, characteristics of the predicates that were used. That information forms the basis for my opinion.
Q. So your opinion that the mesh, the transvaginal mesh itself in the TVT and the TVT-O is the same as the mesh used in the TVT-Secur?
A. Well, the mesh -- the fundamental characteristics of the material is the same. Of course, the mesh dimensions, the final configuration of the device is different, somewhat different. That's why it was a traditional 510(k) and not a special 510(k).
Q. What is your understanding of the differences between the mesh used -- not talking about the size -- the mesh used between the TVT and the TVT-O and then comparing it with the TVT-Secur?
A. Repeat your question so I can understand it.
Q. You said the fundamental characteristics of the material is the same related to mesh. I'm trying to appreciate -- I'm trying to gain an appreciation for what your understanding is between the mesh that was used in the TVT-Secur and the mesh that's used in the TVT and the TVT-O,

Page 61

if any.
A. Well, you're still talking about Prolene mesh that's used in the prior devices for which -- by that time, you're looking at years of experience with that particular Prolene mesh. Of course, there's a colorant in there.
Q. Were you finished?
A. No. So as far as the mesh itself, of course, there's different -- the TVT-S had the Vicryl PDS -- they call it fleece -- components at the end of the mesh. That was different because of the nature of the insertion into the muscles, into the structures.
Q. I understand insertion mechanism is different and the Ethisorb component was different. My question relates to the mesh itself. Is it your opinion that the mesh was the same?
A. I think it was fundamentally the same, yes.
Q. Is it your opinion the tensile strength of the mesh between the TVT and TVT-O versus the TVT-Secur was the same, or do you have an opinion?
A. I'd have to look at the engineering data again to see. On any given day you can have a

little variation. To say it was exactly the same in the test, I'm not certain. But it certainly would have been in the range because we're still taking about the same pore size, as I recall.

Q. I want you to tell me any differences you're aware of between the TVT and the TVT-O versus the TVT-Secur that you're aware of sitting here today.

A. We're talking, first of all, about the material itself.

Q. Any difference you'd like to identify, sir.

MR. HUTCHINSON: Are you talking about the material?

MR. LUNDQUIST: Any difference.

BY MR. LUNDQUIST:

Q. We've talked about the Ethisorb.

A. There are other differences.

Q. I'll give you the Ethisorb.

MR. HUTCHINSON: You're talking about other than the ones he's already described; correct?

MR. LUNDQUIST: Yes.

A. You have different lengths, different dimensions, different accessory devices. I'm not

a doctor, but there was a different surgical technique.

BY MR. LUNDQUIST:

Q. I appreciate you're not a medical doctor. In your role at the FDA, you wouldn't make a determination whether a 510(k) product raised new issues of safety or effectiveness from a medical standpoint, true?

A. Not as a doctor, no. But certainly we get input from the many physicians, like Dr. Herrera and Dr. Lerner, for opinion on that if they were on my staff. I always got medical opinion on 510(k) when there was a clinical issue.

MR. HUTCHINSON: We've been going about an hour.

MR. LUNDQUIST: Nonresponsive after "no."

MR. HUTCHINSON: Are you at a good spot?

MR. LUNDQUIST: Now is just as fine as any.

(Recess from 10:43 a.m. to 10:57 a.m.)

BY MR. LUNDQUIST:

Q. We were just talking about the clearance process related to issues of safety and effectiveness from a medical standpoint, sir. And

I want to make something else clear. Providing any sort of medical assessment of the literature, the medical literature would be beyond your expertise, true?

A. I think to give it a full treatment, yes. Now, when I say full treatment, certainly I can look at -- correlate certain literature aspects to labeling or to considerations by the medical directors, what did they evaluate, was this an appropriate clinical expert report, did they look at current literature, did they look at all available literature, things of that sort, was there literature pro and con.

Q. Fair point, sir. That gets into your previous testimony that you can say there are some articles that would have supported clearance, but in terms of getting into the medical assessment of the literature, that's not your area of expertise, true?

A. I'm not a doctor. In addition, of course, any impact on the risk management assessment, I'd be very interested in that, which I did see.

Q. You're not planning on interpreting any clinical data on the TVT-Secur to opine from a

medical standpoint if the data was adequate for a completely new type of TVT device in this case?

MR. HUTCHINSON: Object to form.

A. Well, your setup there was from a medical point of view.

BY MR. LUNDQUIST:

Q. Yes, sir.

A. I'm not a doctor, so I wouldn't be evaluating it from a medical doctor point of view. I would evaluate it, for example, on those areas where I have expertise. Is this a randomized controlled trial? Is this the sort of setup for an appropriate study?

You know I was the director of the investigational device staff for a time and a staff member where I did evaluate clinical studies for a number of years. And even in device evaluation, that was one of my obligations as a premarket evaluator.

Q. So the interpretation of clinical data is something you would have relied on other doctors within the FDA to do, true?

A. I always relied on physicians when it came to clinical information. But as I said, I certainly had the expertise to evaluate the

Page 66

construction of clinical studies, the sort of analyses that might be derived from the studies based on my own expertise.
Q. Are you talking about just the input into what studies could be performed?
A. Well, was the construction of the study appropriate to support the type of conclusions that were being sought, what was the primary endpoint, what were the secondary endpoints, was the study appropriately powered to evaluate those endpoints. Are the conclusions supported by the data to the extent that I could determine when I felt it went beyond my expertise, I would seek medical.
Q. What study are you aware of conducted by Ethicon with safety as an endpoint on the TVT-Secur prior to launching the product?
MR. HUTCHINSON: Object to form.
A. Prior to launch?
BY MR. LUNDQUIST:
Q. Yes, sir.
A. It was clearned in '05 but it didn't get launched until the end of '06. In that intervening period, there was some clinical experience at that point in time by the time it did get launched.

Page 67

Q. What are you talking about?
A. What am I talking about?
Q. Yes, sir. You're saying there was some clinical experience with safety as an endpoint. I'd just like to know what you're referring to.
A. It was reported later and summarized in the clinical expert reports. I think at the point in time of launch, I think that data was ongoing.
Q. My question was: Are you aware of a study that was conducted by Ethicon with safety as an endpoint on the TVT-Secur prior to launch of TVT-Secur?
MR. HUTCHINSON: Same objection.
A. I think I just answered that. Studies were ongoing, but they weren't published, I think, until later.
BY MR. LUNDQUIST:
Q. What are you talking about?
A. What am I talking about?
Q. Basis for your opinion.
A. I'd have to look at the clinical expert reports. I know that Weisberg's initial evaluation referenced the past history of TVT devices. I don't think he referenced any specific studies of TVT-Secur at that point in time, but

Page 68

then subsequent clinical expert reports did describe randomized controlled studies where those studies would have necessarily had to have been considered, organized and initiated during that period of time between clearance and launch. That's all I'm saying.
Q. I'm still trying to understand what studies you are talking about prelaunch of the TVT-Secur that had safety as an endpoint. I'm not interested in TVT products. I'm talking specifically on the TVT-Secur.
MR. HUTCHINSON: Same objections. Asked and answered also.
A. I'd have to look back at the clinical expert reports to look at those specific studies or publication dates and then work back from there because these studies don't get done overnight. The protocols don't cleared by the institutions, and the patients aren't enrolled given the amount of follow-up that's published in reports.
All I'm saying is that those studies were at least initiated during that point in time.
BY MR. LUNDQUIST:
Q. What were the results -- so the results of that -- so your testimony, let me understand,

Page 69

is that a study with the endpoint -- with safety as an endpoint had, in fact, been initiated by Ethicon prior to launch of the product?
A. I believe so.
Q. Again, you're talking about the five-week study?
A. Well, I'd have to look at the data again. There's a number of randomized controlled studies. Some of them are stretching into 2010 and '11. But safety certainly was an aspect of evaluation in those studies. It may not be the primary endpoint. Certainly it can be a secondary endpoint.
Q. You keep talking about randomized controlled trials. I understand there were RCTs eventually conducted on this device. I'm talking prior to launch. Are you aware of any sitting here today?
MR. HUTCHINSON: Objection.
A. I think I've answered that question.
BY MR. LUNDQUIST:
Q. Well, your answer was I'd have to look at the data again. I'm just trying to understand if you can cite to a single one of them prelaunch that was conducted on the TVT-Secur.

Page 70

MR. HUTCHINSON: He's already answered that question. I'll object to the extent it's been asked and answered. He said he'd have to refer to the clinical expert report.
BY MR. LUNDQUIST:
Q. In a randomized controlled trial, pretty fundamental that some of the opinions you're talking about here are premarket?
MR. HUTCHINSON: Object to form.
A. No, not necessarily. I think that -- to their credit, researchers and Ethicon were evaluating the product all through those years, evaluating the clinical data. FDA evaluated the data in hand at that point in time when they submitted the TVT-Secur.
Now, the TVT-Secur is not entirely a new device. This is -- TVT-Secur is predicated upon the long history of Prolene, the long history from '98 at least of TVT classic. So this is not something new fresh out of the gate as a new therapy for women.
Q. What evidence in hand did the FDA have when they cleared the TVT-Secur specifically related to any type of randomized controlled trial?

Page 71

A. I don't think there was any randomized controlled study referenced in the 510(k).
Q. Are you aware of any?
A. At that point in time, no. But again, that wasn't your question a couple minutes ago.
Q. I assure you it was. I was asking any randomized controlled trial that had been conducted prelaunch of the product.
MR. HUTCHINSON: Object to form. Asked and answered.
A. I did answer that, yes.
BY MR. LUNDQUIST:
Q. So you believe you have expertise in -- is it the creation of randomized controlled trials? What is it you believe you have expertise in, sir, related to the RCTs?
MR. HUTCHINSON: Object to form.
A. In regard to clinical studies, I was the director of the Investigational Device Office for medical devices at FDA. What's the responsibility of that office? To evaluate submissions for clinical studies for new medical devices. What did that evaluation entail? My evaluation of the protocols, the design of studies, the types of data that would be collected, the statistics of

Page 72

the studies, the primary endpoint, secondary endpoints, any other evaluation aspects, the forms that would be utilized to collect safety and effectiveness data, quality of life data, whatever the parameters that were assessed. That was my job.
BY MR. LUNDQUIST:
Q. So you would put these parameters in place, but you were never interpreting any clinical or medical data associated with these submissions, you personally?
A. Yes, I did actually, yes. In my 25 years in device evaluation as the branch chief for general hospital devices and then the director of the division in device evaluation, it's my responsibility to evaluate premarket approval applications on any 510(k)s that included clinical data. To the extent I could review that clinical data without clinical input, I would do so. And that's based upon my expertise and knowledge of clinical studies.
Q. So you're telling me today you believe you have expertise in evaluating clinical data?
A. To a certain extent, yes. You say clinical data. I'm talking about as a person who

Page 73

evaluates the structure and content of protocols to begin to evaluate whether that data, that study may have the opportunity to produce the data that may be expected by the applicant.
From time to time I would need clinical input to evaluate the parameters, to evaluate the endpoints. From time to time I would need an additional statistician to look at the statistical techniques. So it depended to what extent I would evaluate that data.
Q. I'm talking about interpreting clinical data from a medical standpoint to determine whether or not that data is adequate for a new device. You're now saying you believe you have the expertise to do that.
MR. HUTCHINSON: Objection. Been asked and answered.
A. I evaluated premarket approval applications that always contained clinical data. I evaluated 510(k)s that include clinical data to the extent I could evaluate data based upon my experience and training, in evaluating protocols, in evaluating the reporting aspects of studies.
Where my expertise was limited was in regard to certain clinical aspects that required further

Page 74

clinical expertise. What was the clinical significance of certain data, did the conclusions support -- did the data support the conclusions from a clinical standpoint, were the clinical findings significant from a clinician's point of view. So it depended on what I would evaluate.

For example, looking at adverse event reporting from clinical studies, what adverse events were reported, were those adverse events reported consistently and accurately in the conclusions of the report. That doesn't take a clinician in all cases to evaluate.

BY MR. LUNDQUIST:

Q. So if you previously testified that the interpretation of clinical data necessarily required a medical evaluation, you're now saying -- I want to make sure I understand what you're saying, sir. I appreciate the process. You've talked about the basis for the fundamental process where you sign off on the device being cleared. I get that. I want to make sure I understand you because I think you're mixing words a little bit, with all due respect.

I want to talk about the medical aspect itself, the interpretation of clinical data

Page 75

itself. That is not something you would have done while at the FDA, true?

MR. HUTCHINSON: Object to form.

A. I wouldn't evaluate what's required for a clinician to evaluate.

BY MR. LUNDQUIST:

Q. So a medical assessment of the literature on a particular device post-market, that would be something you would have relied on the doctors within the FDA to perform, true?

A. To a certain extent, inasmuch as a doctor's expertise comes into play as Dr. Herrera did, for example, where he understood what he believed to be insertion techniques, for example, of TVT devices, his knowledge of risks and benefits and through his clinical experience he identified a slightly different insertion, technique of implantation.

Not being a doctor, I would not have necessarily had the expertise to appreciate that, as an example.

Q. Have you ever come across a product that was cleared by 510(k) that was ultimately determined not to be safe?

A. Sure.

Page 76

Q. Give me an example.

A. Well, I dealt a lot, for example with -- well, I could pick any number. Let me just give you one. Infusion devices, needles. I was involved as the lead in requiring the needle stick injury prevention components to syringes. There were a lot of needle stick injuries. We were in the midst of -- the beginning of the AIDS crisis, hepatitis. Nurses were being stuck. Doctors were being stuck.

So at the point in time, I insisted that these devices -- and OSHA as well, I worked with OSHA on this -- that for worker safety purposes, these devices have anti-stick components to them. Well, we received about -- I'll just pick a number out just to give you perspective -- maybe 300, 400 different devices of which for safety purposes FDA rejected 300 of them.

I mean, there's more.

Q. You mentioned earlier the method of insertion. Is it your opinion that the method of insertion would have changed the safety profile of the TVT-Secur?

A. Well, it wouldn't -- it wasn't a new type of question because insertion techniques,

Page 77

aspects of application of these TVT devices is a question that's asked for every TVT device. It's not a new type of question. It's not a new risk aspect.

Q. You're talking about intended use?

A. No. Intended use is the first thing you address. The second question you come to in a 510(k) evaluation is comparing devices. Is there anything in that comparison that raises a new type of question.

Q. And your opinion in this case is going to be there was not?

A. There was not, no.

Q. And that's based on what?

A. Based on how I would evaluate the 510(k), and I think Dr. Herrera went down that path of thinking as I've just done. Not to say he wouldn't ask questions about that, not to say I wouldn't ask questions about it, but it's not a new type of question. Where it comes down to is if you have the data, does the performance look the same as the other products. So it comes down to performance comparison, not a new type of question issue.

Q. What data did they have to compare

Page 78

performance?
A. Well, they had the sheep data. They had the other predicate which had been on the market with the same sort of insertion technique as far as my understanding and review of the document was concerned. And so there was not a new type of question.
Q. Same hypothetical. What if different materials had been used, would that change the safety profile of the TVT-Secur?
A. Well, it can be a safety issue. Would it have raised a new type of question? Not necessarily.
Q. Not necessarily. When would it?
A. When would a material?
Q. When would a change in material modify the safety profile as you view it --
A. To become a new type of question?
Q. Yes, sir.
A. Let me just preface by saying the avenue for questioning that leads one down a new type of question avenue, very, very rare you're encountering that in a 510(k), very rare. Less than one percent of all 510(k)s, less than .05 percent. Material is looked at in comparison

Page 79

to other materials, previous materials, predicate materials in terms of engineering tests, in terms of biocompatibility.
It would have to be an entirely new material not seen before where FDA didn't have some experience, where there wasn't a general experience. Of course, we're talking about Prolene here which had been NDA approved, found safe and effective by FDA, had been in TVT-Secur, TVT classic, TVT-O. So you've got that almost now becoming ancient history on Prolene.
Q. What about Ethisorb? That was new, wasn't it?
A. Well, Ethisorb had characteristics of a different type of material. Ethisorb itself, Vicryl PDS, that had been used also in other products. So it wasn't entirely a new product.
Q. What's your understanding of the intended use of the Ethisorb as it had been previously cleared?
A. It had characteristics where it wasn't -- it didn't have the same chronic retention characteristics, chronic -- I call it retention -- characteristics as Prolene. It started to dissolve. There's a little bit of

Page 80

absorption of the product.
Q. Do you know what the intended use of the Ethisorb was as cleared by the FDA?
A. FDA doesn't clear Ethisorb, per se.
Q. So Ethisorb wasn't cleared is your understanding?
A. No. FDA doesn't clear materials. FDA clears products made of materials.
Q. What had the Ethisorb been used for?
A. I'd have to review the files. I know I've run across it before, even before.
Q. Well, the Google gods told me that Ethisorb was used for brains, brain patching. I'm curious what your understanding is of what Ethisorb is supposed to be used for or if you have an opinion.
MR. HUTCHINSON: Object to form.
A. What it can be used for is what is found to be safe and appropriate for the particular clinical application.
BY MR. LUNDQUIST:
Q. Do you have any idea what it had been used for in the past, prior to this fastener mechanism on the TVT-Secur, any idea?
A. I've seen the term before. It wasn't a

Page 81

new term for me. But I'd have to look back at my history and recollection of the material.
Q. Can you name any instance where Ethisorb had been used in a urogynecological setting?
MR. HUTCHINSON: Objection. Been asked and answered, counsel.
A. Again, I'd have to review.
BY MR. LUNDQUIST:
Q. What would you need to review?
A. Well, I'd have to -- I've got files. I've got access to FDA records. I'd have to --
Q. What were you given on Ethisorb from counsel for Ethicon?
A. I don't recall.
Q. Did you do any independent research on Ethisorb?
A. I've seen the material before. That's all I can say as I recall.
Q. Your opinion is that despite not knowing anything about Ethisorb in the past, you're saying the use of that would not have changed the safety profile of the TVT-Secur?
MR. HUTCHINSON: Object to form.
A. That material would have had to have been identified and would have had to have been

Page 82

characterized by Ethicon to FDA and statements made regarding that particular material, either in prior products or the profile of that material.

So you don't just make statements about materials without providing some basis for that material in terms of safety and performance in one way or another.

BY MR. LUNDQUIST:

Q. So as a regulatory expert for Ethicon in this litigation, what basis did Ethicon provide to the FDA to substantiate the safety profile of Ethisorb?

A. I'd have to look at the file. I know this isn't a memory test. So I'd have to look at that material.

Q. It's not a memory test, but, again, understanding that today was the only instance I'm going to have to talk to you about the basis for your opinion. You do appreciate that?

A. Sure.

Q. We've been talking a while about your opinions on the traditional 510(k), that it met all regulations; No. 2, the validation and verification data was sufficient.

Any other opinions in this case, sir?

Page 83

MR. HUTCHINSON: Object to form.

A. Well, just to note again, these things are off the top of my head and may not express all my opinions, especially after I review Dr. Parisian's transcript in detail. I may have more opinions about what she has stated.

I think it's important to explain to the jury the history of Prolene, the acceptance of Prolene as a material being evaluated by FDA initially as an NDA. And that's no simple task to get an NDA approved. It certainly has to include all the information required. Even at that point in time, I evaluated NDAs in the drug evaluation group. And that carried over into being transitioned ultimately to a premarket approval application and then being reclassified, of course.

But the point is this long history of evaluation, the long history of FDA contributing its comments to that evaluation, but also to what labeling requirements FDA found necessary for Prolene and those aspects being carried through even into the TVT products.

And, of course, there's the mesh that came along in '76, there again, being classified as Class II, that it didn't get a free ride into the

Page 84

marketplace in that, ultimately, that group of products had to be evaluated by an expert panel of doctors and classified, which it was.

And the doctors I know because I ran classification panels. They receive a wealth of information on the safety and effectiveness of products in order to base their recommendations for classification. And they had that information and rendered their recommendation it should be Class II and not Class III.

So we have this history. We have this now product line of TVT devices being constructed of that material, and I think that's a very important prologue to the TVT devices. That even continues now. The sutures are still out there, still safe and effective. TVT, TVT-O still out there, still being used, being called the gold standard by professional organizations. So I think there's a good track record.

BY MR. LUNDQUIST:

Q. I'm sorry. You said the TVT-O has been called the gold standard. I've got polypropylene has been used for years. And to some extent, Mr. Hutchinson did a fine job with Dr. Parisian of walking her through basically the history of

Page 85

polypropylene from clearance to present day. I assume you read that portion of her transcript.

MR. HUTCHINSON: Object to form.

A. I'd have to read it again; not in detail.

BY MR. LUNDQUIST:

Q. Polypropylene has been used for years. You said it was a Class II device. Are you saying it was appropriately characterized as a Class II device and that it met regulatory clearance?

MR. HUTCHINSON: Object to form. Mischaracterizes testimony.

A. No. Prolene initially was NDA approved as safe and effective. Then it transitioned over to devices, became a premarket approval application, and then was reclassified, reclassed.

BY MR. LUNDQUIST:

Q. I think you threw in there that TVT is the gold standard. You're not intending on offering any testimony about the TVT being a gold standard in this case, are you?

MR. HUTCHINSON: Object to form.

A. You mean TVT-Secur?

BY MR. LUNDQUIST:

Q. Are you going to testify that TVT-Secur

Page 86

is the gold standard?
A. I'm just reflecting upon professional organization comment. One thing I do remember about Dr. Parisian, she doesn't pull in FDA's evaluation of SUI devices. She doesn't reference professional organization evaluations of TVT devices, which I think is very important.
This is the clinical community and the regulatory community supported by an expert panel of physicians commenting upon TVT devices.
Q. Is it your opinion in this case that TVT-Secur is the gold standard?
A. I don't think TVT-Secur was characterized as the gold standard. But, nevertheless, after all that review and evaluation, FDA took no action to remove TVT-Secur, took no action to seize or enjoin the manufacturer of TVT-Secur, took no action to change the labeling for TVT-Secur.
MR. LUNDQUIST: Objection. Nonresponsive after "gold standard."
BY MR. LUNDQUIST:
Q. I'll strike off TVT-Secur as the gold standard as an opinion.
Any other opinions?

Page 87

MR. HUTCHINSON: Object to form.
A. Well, there's post-market activity. I haven't studied Dr. Parisian's transcript in detail. I'm not sure what she says in there all about --
Q. Let me -- I'm sorry. We previously talked about Dr. Parisian. I'm talking about your opinions now, sir. Do you have any other opinions in this case?
MR. HUTCHINSON: Same objection.
A. All I'm saying is I may object to what Dr. Parisian says about post-market activity.
BY MR. LUNDQUIST:
Q. What might you say?
A. Well, I'd have to study her transcript, but I think it was appropriate that TVT-Secur was not recalled. TVT-Secur was not removed on the basis of a safety issue, TVT-Secur. There was a marketing decision made, and the product was withdrawn from the market.
Q. So your opinion is that -- let me understand because it sounds like you're kind of going back to Dr. Parisian -- that the TVT-Secur was not removed from the market?
MR. HUTCHINSON: Object to form.

Page 88

BY MR. LUNDQUIST:
Q. That is a poor question I'll admit.
Your testimony is that the TVT-Secur was not recalled?
A. It was not recalled.
Q. That it was not removed on the basis of a safety issue?
MR. HUTCHINSON: Object to form.
A. That's correct.
BY MR. LUNDQUIST:
Q. And that the decision to remove the TVT-Secur was a marketing decision?
MR. HUTCHINSON: Object to form.
A. It was a voluntary decision on the part of Ethicon based upon the factors they described to their clients -- to their customers.
BY MR. LUNDQUIST:
Q. Did you look at any of the decommercialization emails or memos to Ethicon employees?
A. I have a number of emails. I'd have to see what you're talking about specifically. I probably have, yes.
Q. Next opinion?
A. I probably covered a lot of ground

Page 89

there. I may have additional opinions.
Q. I want all of them.
A. I know that the patient labeling doesn't come into play here because the plaintiff did not see patient labeling. So any comments Dr. Parisian has on that I wouldn't spend my time on because it's not an element in this litigation, as far as I recall.
Q. Let me understand that. When you talk about patient labeling, are you talking about brochures?
A. Brochures.
Q. And your belief is that Ms. Garcia did not look at any brochures in this case?
A. I read her deposition. I don't see where she -- I think she made an affirmative statement she didn't read any.
Q. What about Dr. Walss?
A. I think he made a statement as well.
Q. Your belief is that Dr. Walss never reviewed any brochures?
A. No, no; provided the plaintiff. I think he might have provided her something on hysterectomy maybe. I'm not sure.
Q. Tell me what your opinions are on the

Page 90

adequacy on the patient brochures.
A. Well, I just said it's not an element here, so I didn't spend a lot of thought and time on that for this litigation.
Q. You're not prepared to render any opinions on the adequacy or inadequacy, for that matter, of the brochures?
A. Well, if it comes to light that plaintiff did read a brochure, I think it's going to be relevant, but as far as I understand, and I may be incorrect, she didn't.
Q. With respect, sir, why don't we let the judge decide what's relevant and what's not. What I am concerned with is do you have any opinions on the patient brochures at all?
MR. HUTCHINSON: Object to form.
A. I probably would if I re-review the material because I've had in the past. But again, I'll have to look at what Dr. Parisian also says to see if I agree or disagree with her on her opinions.
BY MR. LUNDQUIST:
Q. I'm interested in what your opinions are. I'm guessing you're going to disagree with the majority of Dr. Parisian's opinions. I'm

Page 91

trying to understand what Mr. Ulatowski's opinions are on the adequacy or inadequacy of patient labeling.
A. I'd have to look again at the brochures again to see what my opinions would be.
Q. Sitting here today, you can't tell me one way or the other any types of concerns or opinions you have on the adequacy of the labeling?
MR. HUTCHINSON: Object to form.
BY MR. LUNDQUIST:
Q. I'm sorry. The adequacy of the marketing brochures.
MR. HUTCHINSON: Object to form.
A. Well, I can tell you one thing, which is it's my belief that the informed consent process is, in fact, a process that people on the plaintiff's side seem to neglect. Being a process, that means the patient and doctor relationship and communication is of utmost importance, that exchange of information between doctor and patient, explanations, Q and As back and forth. And the brochure, it's not the sum total of information a patient should have or does have ever regarding a device.
What's the basis for my expertise? Well,

Page 92

again, I was the director of the investigational device staff. I implemented the informed consent regulations regarding clinical studies with medical devices and Institutional Review Board approvals of clinical studies. I gave speeches and talks around the country on the informed consent process and informed consent. So fully understood and generally in agreement by everyone and even FDA.
In prior reports I have quotes from the government that says this is a process. And information is just one piece of that that's provided to the patient. So never look at the brochure as a standalone document, as the sum total of information on benefits and risks that a patient is provided.
BY MR. LUNDQUIST:
Q. Aside from your background and your history with these patient brochures, I'm trying to understand if you have any opinion one way or the other as to whether or not the patient brochures of the TVT-Secur were adequate.
MR. HUTCHINSON: Objection.
BY MR. LUNDQUIST:
Q. Either you do or you don't.

Page 93

MR. HUTCHINSON: Objection. Asked and answered.
A. I'd have to look again at the TVT-S brochures specifically to see what they say.
BY MR. LUNDQUIST:
Q. So at trial you may be talking about whether or not the brochure is adequate. Sitting here today you can't tell me; is that true?
MR. HUTCHINSON: Same objection.
A. I have to base my opinion on the evidence and what I've reviewed.
BY MR. LUNDQUIST:
Q. That's all I'm asking you. What's your opinion? Do you have one?
A. I'm saying I have to review that material. I have to review Dr. Parisian's comments on any of that.
Q. Taking Dr. Parisian out of it, sitting here today, you have to review it before you weigh in one way or the other?
MR. HUTCHINSON: That's what the testimony has been. Object. Been asked and answered.
BY MR. LUNDQUIST:
Q. I'm not sure that was actually an

Page 94

opinion. Let me just ask you: Do you have any other opinions?
MR. HUTCHINSON: Other than the ones he already discussed?
MR. LUNDQUIST: Of course.
A. I may have other opinions once I look further at Dr. Parisian's report and as I consider the evidence.
BY MR. LUNDQUIST:
Q. Your opinions.
A. My opinions, yes, yes, and opinions regarding her report.
Q. I appreciate that you're probably going, again, to disagree with some of the things she said. I'm not asking you for everything you may disagree with her on. What I am asking you and what my expectation is under the Texas rules, sir, is that you give me all your opinions sitting here today.
Have we talked about all of your opinions in this case?
A. Not all of my opinions. I would make certain that -- be sure that there's probably an aspect lurking out there that I've considered in prior reports or as I, again, look at the evidence

Page 95

that I may want to get more granular on an opinion or separate out as a separate opinion or identify a different train of thought on an opinion.
Q. When do you think you're going to be able to flush these out, sir?
A. By trial time I'm sure.
Q. Sitting here today though, you've given me all the opinions that you intend to offer, at least, that you can recall in this case?
MR. HUTCHINSON: Object to form and asked and answered.
Counsel, you're talking about outside of the ones he disagrees with Parisian; correct?
MR. LUNDQUIST: I'm talking about his opinions.
A. Well, my opinions are -- we have a different thought process here, but what I think about Dr. Parisian are also my opinions. But, yeah, I may have additional opinions once I further evaluate. I haven't seen the entire VHF, for example. If I receive that and evaluate that, I may have additional opinions.
BY MR. LUNDQUIST:
Q. Let me tell you a little piece of information you may not be aware of. Our

Page 96

discovery deadline ended yesterday in our case. So they can give you whatever else they want to, but that's not necessarily going to bother me at all.
What I'm interested in sitting here today after the close of discovery is: Do you have any other opinions, not related to Dr. Parisian, but does Mr. Ulatowski have any other opinions that have not been expressed either today or in any of your previous depositions relative to the regulatory process?
MR. HUTCHINSON: Same objection.
A. I would think there are, but that's going to depend upon my evaluation of the previously provided material and then any comment I may have on Dr. Parisian in addition to those.
BY MR. LUNDQUIST:
Q. I've not seen you discuss in your previous depositions the 522 orders. And to be fair, since that is in your designation or that is in the defendants' designation of expert, I do want to talk to you briefly about that.
Do you have any opinions relative to the 522 order Ethicon received on the TVT-Secur?
A. Well, first of all, you have to

Page 97

understand the 522 orders are orders for the generic type of device. It's not directed specifically to TVT-Secur, Ethicon, for example. It's for that group of devices.
So anything FDA believes to be of concern regarding that group of devices, whether or not Ethicon has more information to offer or not, really makes no difference when generating the 522 order. It makes no difference to FDA at the initial stage. Do you understand what I'm saying?
Q. I do. I'm just trying to understand what your opinions are.
A. It's a group order. I'll call it class action. And did Ethicon respond thoroughly to the call, 522 call? Yes. They provided a response to FDA within the time required by the order, information to address the questions in the order. There was back and forth between Ethicon and FDA.
Ultimately, it was Ethicon's decision not to pursue the 522 study. I think they had valid reasons. I've seen those reasons before in 522 studies.
I've been the initiator of 522 orders that have issued for devices. Like TMJ implants was a 522 order device, which I regulated. So Ethicon

Page 98

responded adequately, decided not to pursue the study for good reasons, and ultimately made the voluntary decision to withdraw the product. 522 order essentially canceled.
Q. What were their reasons?
A. If you look at the notice to their customers, they had -- with any manufacturer, of course, they're going to have -- be interested in the viability of the product as a marketable product, are you selling enough product, where is the market going in sales. I think, from what I can gather from emails and from that notice, that the market wasn't favorable.
Now, I'm not a person that deals with the money side, but I can understand that as being a valid reason, where there's a sufficient return on investment.
Now, the 522 studies, I think, are quite -- the order was quite complex. The follow-up and the expected data collection, quite complex. That had to play into the ROI as well.
MR. HUTCHINSON: I didn't understand that.
THE WITNESS: ROI, return on investment.
A. And thirdly, they spoke to the litigious

Page 99

atmosphere with their products. And, yeah, that's got to play into considerations as well. So I thought those were all valid reasons as well. If FDA thought given those reasons, which they were, that besides that, the order should persist, the company should be driven to do the study, then FDA would have followed through with that. FDA did not do that.
BY MR. LUNDQUIST:
Q. What about the 522 orders Ethicon received on other products, do you have any understanding as to whether or not they elected to conduct 522 studies on other devices?
A. I don't think they did decide to continue. They voluntarily decided not to pursue those.
Q. Every device they received a 522 on, they voluntarily decided not to continue selling those?
A. Not unusual. Again, I'm not the money guy, but I know how the market waxes and wanes. In the medical device area, there's a very short life cycle on most devices, meaning when a product is developed and when it's marketed, how long it's marketable. I know TVT classic and O have enjoyed

Page 100

a somewhat unusual market life actually. But most devices, the best you get out of them is two or three years or four years at most.
Q. I guess inherent in your previous answer, you're obviously aware that Ethicon chose not to perform any studies on the TVT-Secur in response to the 522 order?
A. I think I said that they didn't pursue those studies, yes, ultimately.
Q. Who's ultimately responsible for assuring a product is safe?
MR. HUTCHINSON: Object to form.
A. What's your definition of safe?
BY MR. LUNDQUIST:
Q. What's your definition of safe?
A. My definition is FDA's definition.
Q. So you're telling me that the FDA is ultimately responsible for ensuring a product is safe?
A. No, no, that's not what I said. I was questioning what do you mean by safe. I told you I'm using the FDA's definition of what is safe. Now, given that, who's ultimately responsible? The manufacturer is responsible for demonstrating through data and information that their product is

Page 101

safe when it's marketed and that it continues to be safe and effective while it's marketed.
Q. That's not a shared responsibility with anybody including the FDA, true?
MR. HUTCHINSON: Object to form.
A. FDA has a role. FDA is the overseer. FDA is the evaluator of the data to provide that marketing entree of the product. FDA oversees the life cycle of the device through inspections, through post-market MDR reports. FDA is not a bystander. FDA is there actively engaged.
BY MR. LUNDQUIST:
Q. You're telling me, Mr. Ulatowski, that the FDA is responsible in some shape or form for the safety of products that are cleared?
MR. HUTCHINSON: Object to form.
A. FDA has been given the responsibility to help ensure the safety and effectiveness of devices. That's a statutory obligation on the part of the FDA.
BY MR. LUNDQUIST:
Q. It's not just Ethicon that's responsible for ensuring the device is safe. You're telling me FDA also is ensuring that the device is safe.
MR. HUTCHINSON: Object to form.

Page 102

A. Your initial question, sir, was who is primarily responsible I think was your question. I think the manufacturer has primary responsibility for providing, assembling and providing evidence, having evidence on the safety and effectiveness of their product. But FDA is, by no means, a bystander in that process.
Q. By signing off -- the FDA doesn't do testing itself on these devices, does it?
A. FDA does have a laboratory that does forensic testing of devices.
Q. What testing did they do on the TVT-Secur?
A. I'm not sure if they did any testing. I just don't know.
Q. I want to make sure I understand because this is the first time I've heard this. You're telling me that FDA has a shared responsibility with Ethicon to ensure that a device like the TVT-Secur is safe?
MR. HUTCHINSON: Object to form.
A. Look at the mission of FDA. The mission of FDA is to help ensure the safety and effectiveness of products on the market. They're fulfilling their mission. How do they do that?

Page 103

Well, they have -- I mentioned some things.
BY MR. LUNDQUIST:
Q. Right. But in the TVT-Secur's example, they only relied on the information provided by Ethicon to them; right?
MR. HUTCHINSON: Object to form.
A. FDA doesn't rely on what they're given. Otherwise, I don't know why we did thousands of inspections every year. We go out there. Ethicon was inspected.
BY MR. LUNDQUIST:
Q. TVT-Secur.
A. You go out.
MR. HUTCHINSON: I'm sorry. I don't know if that's a question pending or not.
Mr. Ulatowski, you can finish your answer.
A. One of FDA's means of ensuring the safety and effectiveness of products is by inspection of facilities. What do those inspections involve? The evaluation of design history records, post-market reporting, manufacturing records. I believe Ethicon was inspected.
BY MR. LUNDQUIST:
Q. Did they do that in the TVT-Secur instance, sir?

Page 104

A. You don't necessarily have to say it's specific to TVT-S because when you look at procedures and policies regarding design history, regarding post-market surveillance, those same policies and procedures relate to every product manufactured in that facility.
MR. LUNDQUIST: Nonresponsive.
BY MR. LUNDQUIST:
Q. Did they inspect any facilities in the TVT-Secur instance, sir?
MR. HUTCHINSON: Objection. Been asked and answered.
A. I'd have to look again at that inspection history, but I know Ethicon has been inspected. In fact, I initiated inspection of Ethicon as director of compliance.
BY MR. LUNDQUIST:
Q. So you don't know if they initiated any of these inspections you've been talking about?
MR. HUTCHINSON: Objection. Been asked and answered twice, counsel. Let's move on.
BY MR. LUNDQUIST:
Q. Again, sir, you keep saying you got to look at things. I want to make sure -- I want the record to fully appreciate that today is your day.

Page 105

Today is my day to find out everything you know. Today is your day to try to explain it to me. I've read your previous transcripts.
I want to understand everything you're going to be opining about the Secur. Again, with that predicate, I'm going to go back to the 522 you're talking about here.
Was it scientifically feasible for Ethicon to conduct a randomized controlled trial prior to marketing the TVT-Secur?
MR. HUTCHINSON: Object to form.
A. Well, inasmuch as that incurs a lot of different aspects on feasibility, I can't say for sure one way or the other. I think there's many different aspects to that question.
BY MR. LUNDQUIST:
Q. What do you consider a long-term study, sir?
A. Well, that varies based upon I'll call it industry practice or past history with FDA submissions. Long-term can be as short as one year. It can be longer depending on the clinical -- what's clinically important for a particular type of study. So it's an "it depends" kind of answer.

Page 106

Q. You mentioned some of the reasons why their rationale for adequately and timely responding to the 522 or ultimately making a decision to decommercialize it.
From your review of the internal Ethicon documents, are you aware of any safety or efficacy concerns expressed about the TVT-Secur?
A. Safety concerns?
Q. Expressed by Ethicon employees internally based on your review of the documents.
MR. HUTCHINSON: Object to form.
A. I think there's commentary in the emails regarding characteristics of the TVT-Secur, the performance and aspects of how to address ongoing information that's being collected by Ethicon. This is kind of the normal way products unfold and the sorts of information one gets and how one reacts to that information that you see in virtually every product.
BY MR. LUNDQUIST:
Q. I'm just trying to understand. In 2012 are you aware of any internal documents from Ethicon that reflect any safety or efficacy concerns with respect to the TVT-Secur?
MR. HUTCHINSON: Object to form.

Page 107

A. When you say safety or efficacy concerns, a company like Ethicon, to their credit, was monitoring the performance of their product in the marketplace as they should, identifying areas where performance was excellent, identifying areas where performance was less than desirable and identifying measures to improve performance and safety, to the extent possible, which is how a company should react to information.
So the answer is yes, as far as obtaining clinical information and responding to that information.
BY MR. LUNDQUIST:
Q. What measures were identified to improve performance and safety on the TVT-Secur?
A. Well, I think part of it is going to require clinician input because it concerns technique, concerns knowledge of the physicians and training of the physicians. So I'm knowledgeable about those efforts. I think the full evaluation of that would probably require a physician's treatment evaluation.
Q. Let me ask you a slightly different question, sir. Are you aware that one of the concerns expressed -- strike that.

Page 108

Are you aware based on your view of the Ethicon internal documents that one of the concerns expressed by Ethicon employees with respect to the TVT-Secur was that it had a higher incidence of failure rates and mesh-related complications as compared to the TVT and the TVT-O?
MR. HUTCHINSON: Object to form.
A. I don't recall specific emails regarding that. I think that clinical data, clinical studies, published studies will have various outcomes. Some studies were very supportive in comparisons. Some studies were not as supportive. That's kind of the waxing and waning of published studies on new devices such as this. And the company was assessing that, analyzing and responding.
MR. LUNDQUIST: Nonresponsive after "I don't recall."
BY MR. LUNDQUIST:
Q. I want you to assume with me that internally Ethicon had expressed those concerns that we talked about a moment ago. Wouldn't that have been important for your opinions in this case?

Page 109

A. Well, after 40 years of looking at documents, manufacturers and how they conduct their business when they market a product, this is sort of the flow and evolution of how things work post-market.
You obtain clinical information. You see some things that are working well. You see some things that are not working well. Is it a certain area that's not working well? Is it a certain type of doctor? Who trained the doctor?
The important point is getting that information, assessing it, reacting to that information, which Ethicon did. Were there concerns about particular areas not having performance that was as desirable as expected? Yes. But not unusual in my experience over the years.
Q. So if internally they were saying that the TVT-Secur was associated with higher complication rates, to you that would not be important in rendering your opinions in this case?
A. No. First of all, you say it too generically. I think what I'm saying in response to that is that you look at all the data. You assess it. You try and do an analysis, call it

Page 110

root cause analysis, what's going on, what is the problem, how do we react to that problem, is there fundamentally an issue with our product where the benefit/risk profile has now changed, and that's what Ethicon was doing.

And in my view based upon the data that I evaluated, Ethicon was doing what it was supposed to be doing in analyzing that data and reacting to that data.

Q. What do you mean they were -- let me back it up. Based on your experience with the FDA and in industry, if a manufacturer of a medical device undertook a duty to perform a premarket randomized control trial, is it your belief they should have done so?

MR. HUTCHINSON: Object to form.

A. Can you give me that question again?

BY MR. LUNDQUIST:

Q. Sure. Based on your experience with the FDA, if a manufacturer of a medical device undertook a duty to perform a randomized control trial, is it your belief they should have done so?

MR. HUTCHINSON: Same objection.

A. I guess I'm not understanding.

Page 111

Q. Based on your experience with the FDA, if a manufacturer of a medical device undertook a duty to perform a premarket randomized controlled trial, is it your belief they should have done so?

MR. HUTCHINSON: Object to form.

A. Again, I'm not understanding the question.

BY MR. LUNDQUIST:

Q. The manufacturer starts to --

A. Restate.

Q. If they tell somebody they're going to undertake or start a randomized control trial, do you think they should do it?

A. Not necessarily.

Q. Why not?

A. Depends on -- it's a case-by-case thing. Why do you want to do the study? Is the study feasible? Can it be funded? Is it feasible from collecting a sufficient number of investigators, enough patients in both randomized groups. There's lots of issues there that may come into play. There's probably double or triple the issues once I put my mind to it. Do we want to conduct it? Why do we want to conduct it? What

Page 112

additional information is it going to provide? Is it better to -- are there already studies ongoing with investigators in the field? There's lots of issues going on.

MR. HUTCHINSON: We've been going about another hour.

MR. LUNDQUIST: I'm almost done.

BY MR. LUNDQUIST:

Q. You said would it have been economically feasible. Strike that.

Would it have been scientifically possible for Ethicon to conduct a randomized control trial on the TVT-Secur prior to launch?

MR. HUTCHINSON: Object to form. Been asked and answered.

A. I don't know because I'm not privy to all the variables that come into play.

BY MR. LUNDQUIST:

Q. You're not going to offer any opinions one way or the other on that?

A. Not without knowledge of all the variables that come into play. And I know a lot of variables come into play because I was asked that of probably hundreds of manufacturers regarding studies when I demanded they do those

Page 113

studies or whatever.

Q. If Ethicon told some of its key opinion leaders that it was going to conduct a randomized controlled trial in this case on the TVT-Secur and they didn't do so, you don't have an opinion on that for trial.

A. I'd have to know the context of that, why they didn't do it. Certainly there were a number of randomized controlled studies conducted.

Q. I'm just trying to understand if you're offering an opinion or not. If you're telling me you need to review more documents, we'll leave it alone, and that will be the record. But I'm just trying to understand if you have an opinion one way or the other.

A. I'd have to know the specifics of that particular incidence. I, again, use the word launch. It was cleared, but it wasn't launched until almost a year later.

Q. Would you agree that the 522 was issued by the FDA because the FDA had concerns about the safety and efficacy of the TVT-Secur?

MR. HUTCHINSON: Object to form.

A. I disagree with that.

Page 114

BY MR. LUNDQUIST:
Q. Why?
A. It was a generic concern regarding the mini tapes. It wasn't directed necessarily to TVT-Secur. It was directed to that group of products. So the panel -- if you look at the panel recommendations, they don't say TVT-Secur we need a 522. You'll never find that.
Q. So that group of products then, would you agree the 522 was issued by the FDA because the FDA had concerns about a group of products which included the TVT-Secur relative to the safety and efficacy?
MR. HUTCHINSON: Same objection.
A. They had a concern that they wanted to see additional data on those products. But again, what data did Ethicon have itself on its product. You kind of get thrown into that hopper with everyone else when it comes to a 522 order.
BY MR. LUNDQUIST:
Q. Again, one of the concerns when you get a 522 is because the FDA, regardless of whether it's 1 or 20 devices, they had concerns with the safety and efficacy of those devices that were subject to the 522. Is that a true statement?

Page 115

MR. HUTCHINSON: Been asked and answered. Objection.
A. I think their concern as expressed in the minutes was they wanted to see some longer-term data.
BY MR. LUNDQUIST:
Q. Nothing to do with the safety and efficacy then, that's your opinion?
MR. HUTCHINSON: Same objection.
A. I think it was mainly the longer-term data issue.
BY MR. LUNDQUIST:
Q. My question was: It had nothing to do with the safety and efficacy?
MR. HUTCHINSON: Counsel, that's been asked and answered.
A. Well, longer-term data, you get more information on safety and effectiveness, but that's any relationship.
BY MR. LUNDQUIST:
Q. Well, one purpose of the 522 that was issued in 2012 was that they were trying to collect long-term data on the safety of a group of devices which included the TVT-Secur; right?
A. Collect additional data on that type of

Page 116

device.
Q. Which included long-term safety and efficacy data, true or not?
A. The type of data collected would have been quality of life data, other adverse event data, yes.
Q. Which includes safety and efficacy?
A. Those are safety parameters.
Q. And there's a reason why they're seeking this information; right? They're not just doing it for fun.
MR. HUTCHINSON: Objection. Form.
BY MR. LUNDQUIST:
Q. They had a concern with this group of devices, true?
MR. HUTCHINSON: Same objection.
A. Well, their expression was that unlike the multi-incisional slings, they didn't have quite enough data on the mini slings, the single-incision slings. So they wanted more data on them.
BY MR. LUNDQUIST:
Q. So the data that would have been collected -- that the FDA was attempting to collect on this long-term information, long-term

Page 117

safety and efficacy data that you agree was being sought, that's the same data that Ethicon could have conducted or could have done premarket on the TVT-Secur, true?
MR. HUTCHINSON: Object to form. Also been asked and answered several times by counsel.
A. I think a manufacturer looks at what they need to do very early on, and it's documented in the design history file, what's the regulatory strategy here, what's our basis of safety and performance of this new device, which is TVT, TVT-O, and what's new here and what kind of studies do we have to do to evaluate this new configuration. The animal studies, the cadaver studies.
So they looked at the difference. They evaluated what data do we need, and they performed those studies.
BY MR. LUNDQUIST:
Q. What long-term safety and efficacy data was available prior to the launch of the TVT-Secur?
A. I think you asked that before. I don't think there was any clinical study data submitted at the point prior to the clearance of the product

Page 118

for TVT-Secur.
Q. So Ethicon was ordered by the FDA in 2012 to conduct long-term -- to conduct clinical trials, to gather long-term data on the safety and efficacy of the TVT-Secur that they could have conducted prior to ever selling the device; is that a true statement?
MR. HUTCHINSON: Objection. Counsel, that's been asked and answered now at least three or four times.
MR. LUNDQUIST: I promise you when the judge looks at this transcript, she'll see it has. I'd just like a short answer to my question.
MR. HUTCHINSON: I know you do, but the that question has already been asked and answered several times now. So we can take a break. We'll do that. But that question has been asked and answered.
BY MR. LUNDQUIST:
Q. Is that a true statement, sir?
A. I don't think there was any motivation for that prior to clearance of the product and submission to the FDA.
Q. You mentioned MAUDE reporting. What is that? You mentioned that at the very beginning of

Page 119

your deposition.
A. Maude is the database. MDR reporting is the reporting.
Q. My apologies. You said you had looked through some MDRs in this case with respect to the TVT-Secur.
A. Correct. I had been provided a lot of data on so-called issue reports that either were submitted as MDRs or were not submitted as MDRs.
Q. Are you going to be rendering any opinions in this case of how many MDR reports that were reportable but never actually reported with respect to the TVT-Secur based on your review?
A. I think I have some notes on that. So I may.
Q. What are you going to say?
A. Typically in my review of those reports, if I look back in my notes, the sorts of issue reports that do not end up as reportable are the sorts of events where medical intervention is not required, where there's a bladder nick, where there's some self-correcting adverse event, something resolves over time, where there's no long-term or medical intervention required or there's some breakage of the inserter or something

Page 120

of that sort, some doctor sees something that's reported in the history report, package broken, and things like that.
So there's always a number of issue reports that relate to things that are out-of-box issues or are accessory issues that are identified by the doctor or there's outcomes of the patient where there's resolution of the issue that is typically not a reportable event.
Q. Why are MDRs required?
A. To provide FDA information on the performance of products in the marketplace.
Q. In your role at the FDA, you relied on the clinical knowledge of medical officers and the M.D. center director to interpret MDRs for trends; is that true?
MR. HUTCHINSON: Object to form.
A. No, not necessarily. In my 25 years in device evaluation, actually one of the jobs of the branch chief was to receive and evaluate the MDR reports for that week for their products.
So I would go through all the MDR reports submitted for the products that I evaluated to understand what sorts of events were occurring so that then I could consider those events in my

Page 121

evaluation of new products.
BY MR. LUNDQUIST:
Q. Are you telling me you personally looked at MDRs for trends?
A. Sure.
Q. And you didn't need to rely on the clinical knowledge of medical officers and the MDR center director to interpret the MDRs for trends is what you're saying. You could have done that independently?
A. I could have done that independently because -- well, sometimes. Depending on the issue, you may need a medical opinion on how something was characterized or reported or whether it was, as I said, medically resolved, some clinical issue that I didn't have expertise on.
But as far as reporting of an event, those events are characterized in the reports. You can do trending on those reports. In fact, the manufacturer when inspections occurred or when PMA supplements were submitted, those sorts of follow-ups and histories were submitted to FDA.
Q. I think I appreciate where you're coming from. You would agree that you don't have the background to discuss health risk assessments or

Page 122

the relevance of certain information and complaints as it relates to patient risks or impacts on patients, true?
MR. HUTCHINSON: Object to form.
A. No. I participated in hundreds of health risk assessments. It's a team effort where you have a clinician, an engineer and others involved in the particular product area that together -- come together to discuss the performance of a product for whatever reason.
I know Dr. Parisian speaks to health risk concerns and things she participated in. I guess she worked at FDA for four years or something.
BY MR. LUNDQUIST:
Q. Sure.
A. Imagine what I did in 25 years working in device evaluation.
Q. Dr. Parisian is a medical doctor. You understand that, sir?
A. Yes.
Q. In fact, Dr. Parisian is the precise type of person that you would have had to rely on to conduct any type of medical assessment of these health risk assessments that were done, true?
MR. HUTCHINSON: Object to form.

Page 123

A. The clinician had certainly an input in those health risk assessments, but they weren't the only input. There was always an engineering analysis. There was MDR analysis. There was premarket analysis of information submitted. There was inspectional analysis.
BY MR. LUNDQUIST:
Q. When it came to the impact, the analysis of a medical risk impact on patients, you're not going to disagree that the clinician was the primary individual that would have had, as you put it, input in these situations, true?
MR. HUTCHINSON: Form.
A. Clinician had the important role, yes.
BY MR. LUNDQUIST:
Q. They were the primary import of these things, weren't they?
MR. HUTCHINSON: Same objection.
A. It would depend on the risk assessment on who was primary, what was the issue involved. It may have been a manufacturing or an engineering issue that was a primary issue at hand.
BY MR. LUNDQUIST:
Q. What's your basis of opining that -- what experience, background, what's your basis for

Page 124

suggesting that you were able to interpret the relevance of clinical information in health risk assessments?
A. Well, it's as done in a company. There may be a clinical outcome, some clinical aspect, but ultimately the root cause relates to an engineering or design or some aspect that goes beyond or that's really behind all the clinical outcome aspects.
So you may have a clinician evaluating the effect to the patient, but then you have to bore in and go back to ultimately the design, engineering, production of the product to fully appreciate what's going on.
Q. But in order to ever be able to evaluate what the possible harm might be by these root causes that are identified by the engineers, you necessarily have to have medical input into that?
A. There's always a physician or quite often some clinical person.
Q. The answer to my question is "Yes"; is it not, sir?
MR. HUTCHINSON: Objection.
A. Yes. There's always some clinical person that's available, if not at the table.

Page 125

BY MR. LUNDQUIST:
Q. Any other opinions we haven't talked about today?
A. I'm sure there will be, but, again, that takes my evaluation of the data and information and Dr. Parisian's comments.
Q. Any other opinions that you intend to offer at trial sitting here today that you can give me that we haven't already talked about or that aren't expressed in your previous depositions?
A. We talked a lot. Off the top of my head, I'm sure there's other information as I look at the data.
Q. Sitting here today, but you can't give me any more opinions?
A. No, not to be fair to myself for sure.
Q. What else do you intend to do before trial?
A. As always, I prepare myself by looking at the data and the information that I've been provided, that list that you've been looking at. I'm sure there will be meetings with counsel to go over them.
Q. You don't intend to offer any new

opinions prior to trial, do you?
A. Well, based upon that review, I may have overlooked some area that actually deserves an opinion. I'm harkening back to my other reports and things. There may be additional areas that are relevant to the regulatory expertise I possess.
Q. Well, there won't be any more depositions in this case, sir, I assure you, with one exception. I assume you're not going to render any opinions on Dr. Trepeta, are you?
A. No.
Q. Sitting here today, you intend to meet with counsel you intend to re-review the documents on your reliance list. Anything else?
A. I think that that's probably the sum total. I have what I have.
Q. That is true.
MR. LUNDQUIST: I'll pass the witness.
EXAMINATION
BY MR. HUTCHINSON:
Q. Mr. Ulatowski, let's talk about the IFU for a minute.
My name is Chad Hutchinson, and I have the privilege of representing Ethicon in this case.
I want to ask this from a regulatory

perspective. Do you believe the IFU for TVT-Secur is adequate?
A. Yes.
Q. Why?
A. The regulation is precisely in regard to what an IFU must contain. The IFU does contain that information. I've reviewed hundreds of IFUs over my time at FDA, 25 years in device evaluation prior to reviewing NDAs and after that in compliance doing labeling compliance for eight years and now as a consultant for clients as I would at FDA. So I believe that IFU was adequate.
Q. If Dr. Parisian, who is the plaintiff's regulatory expert in this case, believes that the IFU was inadequate, would you disagree with her?
A. Yes.
Q. That's all the questions I have. Thank you.
MR. LUNDQUIST: Thank you for your time, sir.
MR. HUTCHINSON: Cynthia, do you have any questions?
MS. FREEMAN: I don't have any questions. We'll reserve.
(Whereupon, at 12:15 p.m., the taking of

the instant deposition ceased.)

C E R T I F I C A T E
DISTRICT OF COLUMBIA:

I, Ann Medis, Registered Professional Reporter and Notary Public, hereby certify the witness, TIMOTHY ULATOWSKI, M.S., was by me first duly sworn to testify to the truth, that the foregoing deposition was taken at the time and place stated herein, and that the said deposition was recorded stenographically by me and then reduced to printing under my direction, and constitutes a true record of the testimony given by said witness.
I certify the inspection, reading and signing of said deposition were NOT waived by counsel for the respective parties and by the witness.
I certify I am not a relative or employee of any of the parties, or a relative or employee of either counsel, and I am in no way interested directly or indirectly in this action.
IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office this 10th day of June, 2015.

_____
Notary Public

- - - - - -

E R R A T A

- - - - - -

PAGE LINE CHANGE

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

REASON: _____

____ ____ _____

ACKNOWLEDGMENT OF DEPONENT

I,_____, do hereby certify that I have read the foregoing pages, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

_____

TIMOTHY A. ULATOWSKI, M.S. DATE

Subscribed and sworn to before me this _____ day of _____, 20____.

My commission expires:_____

_____

Notary Public